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Research Subject Informed Consent Form

Title of Study:	A randomized controlled trial to study the effects of automated physician directed messaging on patient engagement in the digital diabetes prevention program – Phase 3
Principal Investigator:	Devin Mann, MD NYU Langone Health, Department of Population Health 227 East 30th Street, New York, NY 10016 212-263-9026
Sub investigator:	Katharine Lawrence, MD NYU Langone Health, Department of Population Health 227 East 30th Street, New York, NY 10016
Emergency Contact:	Natalie Henning hibrid.lab@nyulangone.org

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?

The purpose of this study is to find out whether messages from providers (doctors) impact how people use diabetes prevention apps. This includes information on how often and when the app is used, and how likely people are to complete the recommended program.

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

You will be part of the study for 18 months. We expect to recruit 432 participants for this phase of the study.

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

The goal of our study is to understand how messages from providers (doctors) affect how people use diabetes prevention app such as Noom.

If you agree to be part of the study, you will be asked to sign a consent form today. We will also ask you a series of questions, give you further details about this study, and give you information to set you up with dDPP-Noom app.

As part of the study, you are expected to **commit to the one year** digital diabetes prevention program curriculum through the Noom app. The Noom digital Diabetes Prevention Program (dDDP) **app** uses the Center for Disease Control and Prevention (CDC)-approved curriculum that provides educational information, tools for tracking progress toward weight loss, and support from virtual health coaches. Participants must also agree to **receive no-cost text messages**, and complete questionnaires through both regular texting surveys and either phone interviews or online surveys. You may choose to participate in an interview session for the 18 month survey. You will also receive a weight scale, an activity tracker, and a A1c self test kit. You will be expected to continue using these devices as part of the study.

You will be assigned to one of two group of the study at random. This means you have 50% chance to be in either group.

If you are in group A, you will receive a 1 year subscription to the Noom app. You will also receive text messages, emails and from the research team regarding surveys for the study.

If you are in group B, you will receive the same things as group A. In addition, you will get texts about your usage of the Noom app from your healthcare team. Your provider will be able to see your progress in the Noom app and will be able to speak to you about it during your regular scheduled visit.

5. What are the possible risks or discomforts?

There are no known potential risks to the study. Patient participants will be using a mobile health applications and receiving text messages. Participants may feel frustrated when sharing their opinions and completing questionnaires, in which case they will be instructed to skip as they see fit.

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?

All patient participants will receive a free 1 year subscription to the dDPP-Noom mobile health application, which they can use as they please, as well as a digital weight scale, step activity tracker, and self test A1c monitor. In terms of long-term benefits, prior similar research have helped participants

improve their health maintenance, and relationship with their providers, by implementing the suggested health behavior changes using dDPP, and increased provider input in the healthcare decisions.

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

You are free to choose not to participate in the study.

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

You will receive a $10 gift card for completing the 6 month survey and 12 month survey each. If you complete the survey, you will also be entered into a raffle to receive an additional $25 gift card. If you participate in the 18 month interview, you will receive a $25 gift card.

10. Will I have to pay for anything?

There are no costs associated with your participation in this study.

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 or research team 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 when the activities have been completed, and all of your feedback has been collected. If you decide to take part in the study, you may withdraw from participation at any time without penalty or loss of benefits to which you would otherwise be entitled.

This study may also be stopped or your participation ended at any time by your physician, the principal investigator, or 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. To withdraw from the study, send a written notice to the principal investigator or study team member 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.

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, 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.

Certificate of Confidentiality
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information 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, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health (see “Who may use and share information in connection with this study?” section). This means that your research information, including lab results may be included in your NYU Langone Health electronic medical record.

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: NIH-NIDDK
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

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. 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

16. 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 the 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