RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

Protocol Title: E3 Diabetes – Closing the Gap in Diabetes Control

Sponsor(s): Novartis Pharmaceuticals

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Protocol Title: Novartis – Closing the gap in cardiovascular risk: Engage, Empower, Evaluate

Sponsor(s): Novartis Pharmaceuticals

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent (permission) form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to decrease the racial gap in diabetes control in African American

and Latinx patients in our Rush University Medical Center clinics.

If you agree to participate in this study, your participation will last for 24 weeks (6 months). After you complete the program, you will return to your usual care with your primary care doctor in the clinic. We will review your medical chart in 3, 6, and 12 months after you start the program to check your A1C readings from your doctor's clinic. We will also follow up with you at 6 months by phone to ask you to complete a few surveys. You may also be contacted to choose to participate in follow-up studies in the future.

During the visits with our program staff, you will be asked to answer questions about your medical history, knowledge about program information, health behaviors such as diet, physical activity and medications. You may be asked to check your glucose and your A1C. For a detailed description of study procedures, please see the "*What are the activities you will be doing if you participate in this study?*" section of this consent form.

There are risks to you for participating in this study. In this study, there is a risk of loss of confidentiality if your medical information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening.

You may benefit from taking part in this study. Based on experience with similar programs, researchers believe this program may be of benefit to people with diabetes. However, because individuals respond differently to therapy, no one can know in advance if it will be helpful for you.

You have the option to not participate in this study.

<u>Detailed Information</u>: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

<u>Why are you being invited to participate in this study?</u>
You have type 2 diabetes and have had a high A1C reading (greater than 8.0) during a Rush clinic visit in the past year. Your doctor's clinic is participating in the study to improve patients' diabetes control.

<u>How many participants will take part in this study?</u>
About 150 participants are expected to take part in this study at Rush University Medical Center. Participants will be randomly divided into two different groups. Group assignment will take place by rolling a die. No one on the study team has control over which group you will be put into. The study will only work if group assignment is completely random.

<u>What are the activities you will be doing if you participate in this study?</u>
All participants in the study will be asked to complete two 30-60-minute visits. The first visit may be longer because we will review this consent form. The second visit will occur 6 months after you start the study.

At these visits you will:

- Complete a medication questionnaire.
- Complete a social needs questionnaire.
- Complete a questionnaire on trust in the healthcare system.
- Complete a questionnaire on diabetes self-management.

Study staff will review the electronic medical records to collect your A1C lab that shows your diabetes control at 3 months, 6 months, and 12 months following your start of the study.

Your other activities in the study will depend on what group you are in. If you are assigned to Group A, you will be asked to participate in the following activities within the next 6 months:

- Check your blood glucose (sugar) at home with your glucometer. If you do not have a glucometer, our study team will help order you a glucometer which will be covered by your insurance.
- Meet one-on-one remotely with a nurse at the beginning of the program to make sure you have your glucometer supplies (either continuous glucose monitor or fingerstick glucometer supplies).
- Receive lifestyle educational materials with information on how to improve your diet, move more, and self-manage your diabetes.

If you are assigned to Group B, you will be asked to participate in the following activities within the next 6 months:

- Check your blood glucose (sugar) at home with your glucometer. If you do not have a glucometer, our study team will help order you a glucometer which will be covered by your insurance.
- Meet one-on-one remotely with a community health worker over the phone or on a video call to discuss ways of checking blood glucose, how to improve your blood glucose levels and diabetes, how to help you take your medications, and how to make lifestyle changes with exercise, food, and social resources to help you improve your health. You may receive up to 12 calls from the community health worker.
- Meet one-on-one once in person with a pharmacist at the beginning of the program to help set up your glucometer and to make medication changes (if needed)
- Meet one-on-one remotely with our dietician (nutritionist) twice the first month of the program, followed by once monthly for the remainder of the program.
- Meet one-on-one with a community health worker once a month to review your lifestyle goals and help you coordinate medical care.
- Respond to phone calls from our pharmacist to help with blood glucose alerts and medication changes (if needed).
- If you have a finger-stick glucometer, you will need to record your blood glucose numbers by hand and respond to a call from our community health worker every 2 weeks to report your blood glucose numbers. The type of monitor you have will be determined by your diabetes needs and insurance coverage.
- If you have a continuous glucose monitor (Dexcom or Freestyle Libre device), your

numbers will be sent to the pharmacist automatically.
- Respond to phone calls from our social worker if you need additional social resources, which might relate to housing, transportation, food availability, or other resource programs available.

Will your information be used for research in the future?
Information collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, you will not be asked for additional consent.

Will you be contacted about participating in future research?
If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What are the risks and discomforts of participating in this study?
There is little to no risk of participating in this study for you. There is a possibility of loss of confidentiality in the event of a data breach. Data will be stored on secure encrypted servers at Rush University Medical Center to minimize this risk.

Participants might experience symptoms associated with diabetes medications, such as lightheadedness or dizziness, nausea, diarrhea, which are the same side effects and risks as you would experience in the clinic with your doctor. No investigational medications will be used; we will use the same standard of care medications you receive from your doctor. “Investigational” means that it is not approved by the U.S. Food and Drug Administration (FDA) for use. The difference is we will be following you more closely on a regular basis remotely.

There may be risks that may happen that we cannot predict.

What if there is new information that may affect your decision to participate in this study?
During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Will you receive your individual results from the study?
Generally, activities performed for research purposes are not meant to provide clinical information. You will know your blood glucose readings from the home glucometer and will be able to see if you are improving. We may learn things about you from this study which could be

important to your health or treatment. If this happens, this information will be shared with you. The study will not cover the costs of any follow-up actions outside of the study.

Can you leave or be removed from this study?

You have the right to leave a study at any time without penalty. There are no consequences of withdrawing from the study.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold (keep back) or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Pallok and her study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Pallok and her study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. The health information that Rush may use or disclose for this research includes:

- Blood glucose
- A1C
- Medical History

Dr. Pallok and her study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- the Researchers;
- The study Sponsor, Novartis Pharmaceuticals
- Monitoring agencies such as the Food and Drug Administration (FDA), and the National Institutes of Health.

While you participate in the study you will have access to your medical record, but Dr. Pallok is not required to release study information to you that is not part of your medical record. Rush is

required by law to protect your health information, and study records that identify you will be kept confidential. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings. We will ask your permission to take photographs that may be used in scientific presentations.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Pallok, at Associates in Internal Medicine, 1725 West Harrison St, Suite 263, Chicago, IL 606012. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety (the entire time) of this research study. It will expire when the study is completed or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. You will be assigned a random study identification number and all information collected from you will be identified by the random number. No identifying information will be stored with your study data. The file linking your name to your identification number will be kept in a locked filing cabinet separate from your study data.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

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 using the clinical trial number: TBD

What are the costs to participate in this study?

All costs for the required study as well as all assessments will be paid by the sponsor Novartis Pharmaceuticals. Diabetes medications, lab tests and glucometer supplies will be billed to your insurance and supplied the same way as your usual primary care doctor's orders.

The following items and services will be provided to you free of charge: All program costs

You or your insurance will be responsible for paying for the cost of any routine medical care that you would receive whether you participate in this study or not, unless you are told that such item or services will be supplied at no cost. If you have health insurance, the insurance may or may not pay for the costs associated with your participation in this study. You will have to pay for any co-payments, deductibles or co-insurance amounts that your insurance coverage requires. Before you decided to be in this study, you should contact your insurance provider to verify coverage.

Will you be paid for your participation in this study?

You will receive a $45 gift card after the first baseline visit and last study visit at 6 months for your time. This means you may be paid a total of $90 for taking part in the study. If you are in Group B and are required to do an in-person visit with the study pharmacist, you will receive a Rush parking reimbursement of $10.

What if you are injured as a result of your participation in this study?

If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Pallok at telephone number 312-942-6700.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed for medical care provided by RUSH. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Dr. Kristen Pallok at 312-942-6700 or email at Kristen_N_Pallok@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?

Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Pallok in writing at the address on the first page. Dr. Pallok may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT:

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

_____	_____	_____
Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

_____	
Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE BY WITNESS/INTERPRETER:

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant and the person signing the form has done so voluntarily.

_____

Name of Witness/Interpreter

_____	_____
Signature of Witness/Interpreter	Date of Signature