Official Title: A Transition of Care Model From Hospital to Community for Hispanic/Latino Adult Patients With Diabetes.

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DUKE UNIVERSITY HEALTH SYSTEM

Name _____

MRN_____

A Transition of Care Model from Hospital to Community for Hispanic/Latino Adult Patients with Diabetes.

Version date: October 28, 2021

PI. Leonor Corsino, MD, MHS and Blanca Iris Padilla, PhD

CONCISE SUMMARY
The purpose of the study is to develop and test a new process to better help Hispanic/Latino adult patients with Diabetes move from the hospital to the community.

Hispanic/Latino patients with diabetes admitted to Duke Health Systems will be eligible to participate. Patients admitted to the hospital will be enrolled to participate in the study prior to their discharge. Participation includes receiving instructions regarding the management of their diabetes after discharge. Participants will receive a follow up phone call 30 days after discharge. Also, participants will complete an interview after their discharge to share their experience and suggestions to improve the process.

To be included in the study you must be ≥ 18 years of age, self-identified Hispanic/Latino, have Diabetes, speak Spanish or English, be able to provide informed consent and be hospitalized at one of the Duke Health Systems hospital.

You are being asked to take part in this research study because you are Hispanic/Latino and you have Diabetes and you are being treated in Duke Regional Hospital or Duke University Hospital. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the New York Regional Center for Diabetes Translation Research Pilot and Feasibility Program sponsored by the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Leonor Corsino, MD, MHS, and Dr. Blanca Iris Padilla, Ph.D. and their research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Leonor Corsino and Dr. Blanca Iris Padilla will be your doctors for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterward, if needed.

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WHY IS THIS STUDY BEING DONE?

The study is being done to develop and test a process to transition Hispanic/Latino individuals with diabetes from the hospital to their community. There is a need for a culturally appreciate process that address the needs and challenges of the Hispanic/Latino communities with diabetes.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 32 participants will take part in this study from Duke Regional Hospital and Duke University Hospital.

WHAT IS INVOLVED IN THE STUDY?

All participants will be patients with a diagnosis of diabetes that are currently hospitalized and about to be discharged to their community and homes. 16 participants will be discharged and receive a discharge summary that will reflect the newly developed transition of care model. As part of the study, we will ask you to complete a set of questionnaires. The questionnaires will include questions about you, your medical history, sociocultural and social support. 30 days after you are discharged one member of our team will call you and ask you to complete a short telephone survey. In addition, we might call you for follow up interview to ask you questions regarding the process and to get your suggestion on how to make it better. Also, we will look at your medical record to see if you had visits to the Emergency Department or readmissions to the hospital within 30 days after you discharge from the hospital.

The only activities involved with this study are the baseline interview, a phone call at 30 days, and a potential interview after your discharge.

If you agree to be in this study, you will first be asked to sign and date this consent form.

You will meet with Dr. Corsino orDr. Padilla or an authorize member of the team. During the initial meeting, you will be asked to complete a set of questionnaires. Before your discharge you will receive instructions regarding your diabetes care after you get to the community/home. If you are selected for an interview, after your discharge, a member of the team will contact you to schedule an interview with one member of our team. During the interview, we will ask you to share your experience and suggestions to make the process better. This interview will be recorded. Only authorized members of the research team will have access to the recordings. After the recordings are reviewed and transcribed, they will be destroyed. You can still be part of the study even if you do not want us to record the conversation. The questionnaires will ask several questions about you and your culture, language, health knowledge, financial support, social support, insurance status, and comorbidities. 30 days after your discharge you will receive a call from a member of the research team. During the call we will ask you to complete a short questionnaire.

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Please place your initials by your preference below:

_____ I AGREE to have my interview audio recorded.
_____ I DO NOT AGREE to have my interview audio recorded.

Participation in this study is voluntary. Refusal to participate in the study will have no effect on your healthcare at Duke. If you choose to remove yourself from the study before the study is over, you can let Dr. Leonor Corsino, MD, MHS or Dr. Blanca Iris Padilla, Ph.D. know at any time by email TransitionOfCare@dm.Duke.edu or during the study or by sending us a letter to the following addressDUMC Box 3921, Durham NC 27710.

HOW LONG WILL I BE IN THIS STUDY?
Your participation in this study will last about approximately 30 days. We will not contact you for follow up information.

WHAT ARE MY ALTERNATIVES TO PARTICIPATING IN THE STUDY?
This is not a study to treat diabetes. You can simply choose not to participate or to withdraw from the study at any time.

WHAT ARE THE RISKS OF THE STUDY?
This is a minimal risk study and there are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There are no direct medical benefits to participating in this study, but your participation may lead to knowledge that will help other Hispanic/Latinos with diabetes.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by people involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary

information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, the results of your questionnaire and your answers to the questions may be reported to the New York Regional Center for Diabetes Translation Research Pilot and Feasibility Program and the National Institute of Health and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of the New York Regional Center for Diabetes Translation Research Pilot and Feasibility Program, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family 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. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

As part of this study, you will be asked to fill out a questionnaire and answer questions during an interview. The study doctor will use this questionnaire and interview to complete this research. This questionnaire and interviews will be reported to representatives and affiliates of the New York Regional

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Center for Diabetes Translation Research Pilot and Feasibility Program. This questionnaire will not be included in your medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information may be destroyed or information identifying you

will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations. Your name and identifiers will not be attached to any documents disclosed to the sponsor.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Your personal identifying information will not be shared outside of DUHS, because we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect the sharing of private health information.

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.

WHAT ARE THE COSTS TO YOU?

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Leonor Corsino, MD, MHS, or Dr. Iris Padilla, Ph.D. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

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The study sponsors New York Regional Center for Diabetes Translation Research Pilot and Feasibility Program has agreed to pay for services and procedures that are done solely for research purposes. Please talk with the PI/study team about the specific services and procedures that the sponsor will pay for and the ones for which you or your insurance will be responsible.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

WHAT ABOUT COMPENSATION?

You will be reimbursed up to $ 25 for completing the transition of care questionnaires and 5 participants will receive and an additional $10 for a 30 day post discharge interview. for your expenses related to your participation (parking, gas, and time).

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment to

Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Leonor Corsino, MD, MHS at 919-684-4005 durign regular office hours or 919-684-8111 during weekends and holidays and Dr. Blanca Iris Padilla, Ph.D. at (919) 613-9771 Monday through Friday 8 am – 7 pm and at (615) 293-4110 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Leonor Corsino, MD, MHS and Dr. Blanca Iris Padilla, Ph.D.in writing and let them know that you are withdrawing from the study. The mailing address is DUMC Box 3921, Durham NC 27710. The email is TransitionOfCare@dm.duke.edu.

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We will tell you about the new information that may affect your health, welfare, or willingness to stay in this study.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your

identifying information is removed from your data, we will no longer be able to identify and destroy them.

The use of your data may result in commercial profit. You will not be compensated for the use of your data other than what is described in this consent form.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Leonor Corsino, MD, MHS at 919-684-4005 during regular office hours or 919-684-8111 during weekends and holidays. Or, Dr. Blanca Iris Padilla, Ph.D. at (919) 613-9771 Monday through Friday 8 am – 7 pm and at (615) 293-4110 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time