IRB Protocol# 2000031731
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COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY
YALE UNIVERSITY SCHOOL OF MEDICINE
YALE-NEW HAVEN HOSPITAL

Study Title: *Undiagnosed Diabetic Retinopathy: Using Participatory Science to Design an Intervention for Patients at High-Risk for Blindness*
Principal Investigator (the person who is responsible for this research): *Kristen Nwanyanwu, MD, MBA, MHS Yale Eye Center 40 Temple Street, Suite 3A*
Phone Number: *(203) 785-4282*

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to design an intervention for people at high risk of blindness from diabetes.
- Study procedures will include: An intake exam including questionnaires; meetings/calls with a Patient Navigator; follow-up call with a research team member.
- You will also have a standard eye exam for people with diabetes including eye dilation and photos of the retina and an a A1c finger stick test to check your blood sugar levels over the past 3 months.
- 2 in-person visits and 5 phone visits are required.
- These visits will take less than 6 hours total.
- There are some risks from participating in this study. There is a slight risk of loss of confidentiality.
- The study may have no benefits to you. The study may develop an intervention that can help people with diabetes engage in regular eye exams and prevent diabetic blindness. You may benefit from being screened for diabetic eye disease and preventing blindness from diabetes.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

We are asking you to take part in a research study because you have diabetes and have not had an eye exam in the past 12 months. We are looking for **60 participants** to be part of this research study.

APPROVED BY THE YALE UNIVERSITY IRB 1/13/2022

Who is paying for the study?

National Institutes of Health – National Eye Institute

What is the study about?

The purpose of this study is to design an intervention for people with diabetes who are at high risk of diabetic blindness.

What are you asking me to do and how long will it take?

If you agree to take part in this study, this is what will happen:

- You will meet with a member of our research team to sign a consent form and fill out a questionnaire. The questionnaire will ask you about your health, your doctors, and your lifestyle.
- The research team member will take a drop of blood from your finger to test your A1c.
- An eye doctor at Yale Eye Center will give you an eye exam. This will include dilating your eyes so we can take pictures of your retinas.
- We will look back through your medical record to gather information about your diabetes diagnosis, history of diabetes care and eye care, and any medical conditions you may have that are related to diabetes (like high blood pressure, kidney failure, foot ulcers, etc.)
- You will also meet with a patient navigator from Project Access of New Haven, Inc. The patient navigator will assist you will medical appointments.
- At 3, 6, 9, 12, and 18 months after these initial appointments, the patient navigator will call you to check in and assist you with medical appointments as needed.
- While you are enrolled in the study, the research team will check your medical record to see what kind of medical appointments you had recently.
- We may ask you to complete a short interview about your experience in the study. If we ask to interview you, we will ask you for permissionto record you.
- 2 years after you enroll, a member of our research team will call you to see how you are doing and ask you some questions about your experiences in the study.

What are the risks and discomforts of participating?

We do not anticipate any risks or discomforts for participating. There is a slight chance of loss of confidentiality of your information. We will do everything we can to make sure this does not happen.

How will I know about new risks or important information about the study?

We will tell you if we learn any new information that could change your mind about taking part in this study. We will also send all study participants an update about our findings at the end of the project.

How can the study possibly benefit me?

The study may benefit you by screening you for diabetic eye disease and getting you care before it progresses to blindness. You may also benefit from working with a patient navigator who can help you understand your medical care and get to appointments.

How can the study possibly benefit other people?

The benefits to science and other people may include a better understanding of how to engage people with diabetes with eye care and screening that could prevent diabetic blindness.

Are there any costs to participation?

If you take part in this study, you will not have to pay for any services, supplies, study procedures, or care that are provided for this research only (they are NOT part of your routine medical care). The eye exam with dilation and fundus photography and the A1c finger stick are not research procedures because this is routine eye care for people with diabetes. You or your health insurance must pay for services, supplies, procedures, and care that are part of your routine medical care. You will be responsible for any co-payments required by your insurance. There may be additional costs to you. These can include costs of transportation and your time to come to the study visits.

Will I be paid for participation?

You will be paid for taking part in this study. You will receive $25 for completing the eye exam, and $15 for each meeting with the patient navigator 3, 6, 9, 12, and 18 months after enrollment. We will use a Bank of America pre-paid debit card to provide the payment for taking part in the study. We will have to share your name, address, and telephone number with Bank of America for ePayments. You will receive a card in the mail with the first payment. You will need to activate the card over the phone. Each additional payment will be automatically added to your card. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

What are my choices if I decide not to take part in this study?

Instead of participating in this study, you have some other choices.
You could:

- Get routine eye exams without being in the study.

How will you keep my data safe and private?

This research 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 Eye Institute which is funding this project. 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 of child abuse and neglect, intent to harm yourself or intent to harm others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, such as including study related medical information in your medical record.

In order to protect your personal information, once you enroll in the study you are assigned a study ID number. Your name will not appear on any of the questionnaires. We will keep records of your participation in this study protected and confidential. We will lock all study records in the office of the Principal Investigator. All study computers will be password protected. All collected study data or audiotapes will be de-identified within 12 months of study completion.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we will ask you for your permission.

We will also not share information about you with other researchers for future research.

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 Information Will You Collect About Me in this Study?

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- The entire research record and any medical records held by *Yale New Haven Health* created from: *1/1/2021* to: *1/1/2024*
- Data from a retrospective chart review about your diabetes diagnosis, history of diabetes care, history of eye care, history of care for other conditions related to diabetes
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - Eye exams
    - Laboratory and other test results
    - Diaries and questionnaires
    - Interview recordings
- Data collected by the Patient Navigator Program at Yale New Haven Hospital.

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program, and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Principal Investigator of the study
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- The Patient Navigator Team at Project Access of New Haven, Inc.
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to ***Dr. Kristen Nwanyanwu, 40 Temple Street, Suite 3A*** **at the Yale University, New Haven, CT 06520.**

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

What will happen with my data if I stop participating?

If you choose to stop participating, we will no longer contact you for patient navigation appointments or follow-up appointments. We will use any data we have already collected but it will be de-identified.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at **203-785-4282.**

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

If asked to participate in a follow-up interview about my experience in the study, I agree that *an audio recording* may be taken of me as part of the study. The recording will be used for purposes of the study only.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date