H-40322- TECHNOLOGY TO IMPROVE THE HEALTH OF RESOURCE-POOR HISPANICS WITH DIABETES

**Background**

You are invited to take part in a diabetes project as an opportunity to improve your health and diabetes control/prevention. Studies have shown that individuals who participate in diabetes group classes (or visits) have better control of their disease than those who do not. Studies have also shown that having Community Health Workers (CHWs) as an advocate for your healthcare improves outcomes. However, there are limited studies known as randomized controlled trials in communities such as yours to help researchers understand the short and long-term effects of these classes, such as blood sugar levels and patient satisfaction. In addition, there is limited information that guides researchers on how to best train and equip CHWs involved in these classes, such as using telehealth to support them in their work. Please read this information and feel free to ask any questions before you agree to take part in the project.

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.

**Purpose**

We would like to provide an opportunity for you to participate in diabetes group classes that include CHWs. This is an opportunity that we anticipate will improve your overall health, your diabetes prevention/care, and prevent long-term diseases.

**Procedures**

The research will be conducted at the following location(s):
Baylor College of Medicine, Christ Clinic, and San Jose Clinic.

The project will be conducted at the following location(s): Baylor College of Medicine at Christ Clinic (9/2019-12/2020) or San Jose (1/2018-6/2019). We will provide 3-hour classes for adults with diabetes for 6 months. You will randomly be assigned to group A or group B. Group A starts the classes now while group B will start in 6 months. In the meantime for group B, you will receive your usual healthcare at Christ Clinic. Any individuals not in the original randomization but would like to participate in the wait-list control (group B) must be consented prior to participation and their data will not be used in the primary analyses. Classes meet monthly for 6 months. Standard of care/usual healthcare is a diagnostic and treatment process that your provider follows for your diabetes care such as measuring your glucose levels, blood pressure and cholesterol. For the physician encounter, some individuals will meet by video conferencing/telemedicine. There will be a physician on site at all times and you may opt out at any time. CHWs will contact you weekly (e.g., call) to support you and your journey to good health.
For the classes, we will:
1. Check blood work for diabetes and preventive care.
2. Check your blood pressure and weight. You will also turn in your glucose logs from the month before.
3. Provide education about diabetes led by a CHW.
4. Work with project staff in 3 small groups to adjust your diabetes medications (if needed) and offer support or counseling regarding your health. This means that we may discuss medical information such

as your blood sugar, cholesterol, and blood pressure in a group setting at times.
5. Repeat lab work (if indicated) every 3 months or earlier if clinically warrented.
6. Give you questionnaires at 0 and 6 months to understand your treatment satisfaction, emotional distress, and spirituality related to diabetes.
You can see and get a copy of your project related health information. Your project physician may be able to provide you with part of your information while the project is in process and the rest of your information at the end of the project. By participating in this project, you agree that patient information shared in the class is confidential and will not discuss patient information in the project outside of class. For the Cohorts 1,2 those who completed study data (e.g., HbA1c, surveys) are eligible to receive a $100 gift card at the beginning of the project and six-months later (total $200). For Cohorts 3,4 those who attend class are eligible to receive a $20 gift card at each session (six chances total, $120 total)

**Research related health information**

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, Christ Clinic, and San Jose Clinic to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, Christ Clinic, San Jose Clinic, and NATIONAL INSTITUTES OF HEALTH (NIH) and their representatives.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine, Christ Clinic, and San Jose Clinic are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine, Christ Clinic, and San Jose Clinic to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine, Christ Clinic, and San Jose Clinic maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine, Christ Clinic, and San Jose Clinic to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine, Christ Clinic, and San Jose Clinic.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, NATIONAL INSTITUTES OF HEALTH (NIH) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, Christ Clinic, and San Jose Clinic may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Dr. Elizabeth Vaughan
1504 Taub Loop, 2PA-71-009a-m
Houston, TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

**Potential Risks and Discomforts**
Loss of confidentiality is a risk: We will tailor this project to meet your healthcare needs. All information is confidential within the classroom setting and not to be shared with others outside of the class. Project staff will update you in a timely way on any new information that may affect your decision to stay in the project. Project staff will update you in a timely way on any new information that may affect your decision to stay in the project.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

**Potential Benefits**

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand You may receive no direct benefit from your participation in this project. However, your participation may help the investigators better understand the treatment of diabetes. The benefits of participating in this project may be: improved control of diabetes, knowing your individual blood sugar and cholesterol levels and goals, and improving your overall healthcare. .

**Alternatives**

You may choose to not participate in this study.

**Subject Costs and Payments**

You will not be asked to pay any costs related to this research.

For Cohorts 1,2 those who complete study data (e.g., HbA1c, surveys) will be eligible to receive a $100 gift card at the beginning of the project and six-months later (total $200). For Cohorts 3,4 those who attend class are eligible to receive a $20 gift card at each session (six chances total, $120 total)

**Subject's Rights**

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, ELIZABETH VAUGHAN, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: Dr ELIZABETH VAUGHAN at 1-713-873-3970 during the day and Dr Elizabeth Vaughan at 1-713-873-3970 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the

investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

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|---|---|
| Subject | Date |
| Investigator or Designee Obtaining Consent | Date |
| Witness (if applicable) | Date |
| Translator (if applicable) | Date |