

**Date: June 30, 2024**

**Last approval date: June 30, 2023**

**Title: Healthy Communities Through CHW Initiatives**

**NCT #: NCT05965869**

- Hello. Is Mr./Mrs./Miss \_\_\_\_ there?
- Hi Mr./Mrs./Miss \_\_\_\_\_. My name is \_\_\_\_\_. I am a Community Health Worker from \_\_\_\_\_ Clinic (other CHW introduce self too). I work with the clinic \_\_\_\_\_ and Dr. Vaughan from UTMB, and we would like to let you know about a new project that is a free diabetes 12-month program at \_\_\_\_\_. We have done the project in other clinics and found that individuals who participated had better blood sugar, blood pressure, and weight loss than those who did not join. The program includes individualized support from Community Health Workers by phone/text to help improve your diabetes and monthly YouTube videos sent to your phone. You don't need to leave your house to participate, although, we will provide optional education groups at the clinic each month. If you come to the last session, we may check your glucose and vitals, and you will receive a \$50 Walmart gift card when you come. Are you interested in participating?
  - *If they say no:* Thank you for considering. **Write down the reason.**
  - *If they say yes:* Great! Here are a few details:
    - There will be two groups, those in the program and those who remain in usual care in the clinic. Groups are chosen at random, and we will call you again in the next few weeks to tell you your group.
    - You will continue to see your doctor in the clinic as scheduled.
    - There are no major risks of participating, mainly loss of confidentiality, which you may also experience routinely in the clinic. To protect you against this, we use several secure, encrypted resources to protect your privacy. Participation is always voluntary, and you may choose not to participate at any point.
    - A description of this clinical trial will be available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.
    - The University of Texas Medical Branch (UTMB) committee that reviews research on human subjects, the Institutional Review Board (IRB) will answer any questions about your rights as a research subject and take any comments or complaints you may wish to offer. You can contact the UTMB IRB at [IRB@UTMB.EDU](mailto:IRB@UTMB.EDU) or Dr. Vaughan at 409-772-4182.
- Do you have any questions?
  - *Confirm that they are Latino(a) and can understand Spanish.*

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|-----------------------------|-----------|-----------------------------------|
| Printed Name of Participant | Study ID# | Date and Time of Consent Obtained |
|-----------------------------|-----------|-----------------------------------|

|                                       |  |
|---------------------------------------|--|
| Signature of Person Obtaining Consent | Printed Name of Person Obtaining Consent |
|---------------------------------------|--|

I witnessed \_\_\_\_\_ perform the consent process over the phone in its entirety and can attest that the subject gave verbal consent to participate in this study.

|                      |                         |
|----------------------|-------------------------|
| Signature of Witness | Printed Name of Witness |
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