

Project title: South Texas  
Early Prevention Study  
(STEPS) SNAP-Ed

NCT05851144

Original Date 08/02/2022

**Consent Form of Participation**  
**UTRGV - South Texas Early Prevention Study (STEPS)**  
**Supplemental Nutrition Assistance Program (SNAP -Ed)**  
**STEPS/SNAP –Ed project**  
**To be conducted at:**

Pharr-San Juan-Alamo Independent School Districts (PSJAISD)  
La Joya Independent School Districts (LJISD)

**Information about this form**

**“You”** refers to the person providing consent for a child, your next-of-kin or someone for whom you are the legal guardian of or are designated as a surrogate decision-maker on a power of attorney.

Before signing this form, read and understand the research study terms and conditions.

Please, inform the researchers if you are currently participating in another research study.

☐ Yes, I am currently participating in a different study.

☐ No, I am not participating in a different study.

If yes, name it here \_\_\_\_\_

**By signing this consent form, you are agreeing to participate in this research study**

In School years 2022-2023, 2023-2024, and 2024-2025.

**Voluntary Participation** –You may stop continuation of participation in the research study at any time with no penalty involved.

**General Information – “Who is conducting this research?”**

**Project Investigators:**

The Principal Investigator (PI) and Co-PIs are the researchers directing this study; they are responsible for protecting participant’s rights, safety, and wellbeing. From UTRGV Department of Health and Human Performance are PI Roberto P. Treviño, M.D., Co-PIs Dr. Zasha Romero and Dr. Lin Wang, Dr. Lisa Salinas from the Department of Health & Biomedical Sciences and Dr. Juan Lopez-Alvarenga from the School of Medicine.

**Study Sponsor:**

Health Human Service Commission (HHSC)

HHSC is a federal government agency that promotes scientific research by funding this study (the sponsor). The sponsor reviewed the study plan and funded UTRGV researchers to conduct this study.

**Purpose of this study – “Why is this study being conducted?”**

Researchers believe that through school health education and the modeling of healthy behaviors, children will be prepared to make healthier choices, thus, helping reduce childhood obesity in the RGV. UTRGV researchers are supported by PSJA and La Joya Independent School Districts in conducting this study.

This research study is focused on decreasing childhood obesity and increasing physical activity and dietary intake of fruits and vegetables. The Bienestar Coordinated School Health Program (BCSHP) will be implemented in selected schools. The Social and Health Research Center (SAHRC), the creator of the BCSHP program, will provide instruction on the implementation; and UTRGV will measure its effectiveness. The BCSHP combines an instructional portion of health, nutrition and physical education classes for students, a series of meetings for parents/families, and staff development for the child nutrition services department. The four school components participating in the project are teachers, physical educators/coach, parental engagement liaisons, and the child nutrition services department. Along with the components, the ISD administrators, school principals and front desk staff will help and provide recommendations for improvement of the program.

### Information about Study Participants

#### “Who is participating in this research?”

You are invited to participate in this study because your child is enrolled in one of the participating elementary schools in PSJA ISD or La Joya ISD.

### Information about Study Procedures

#### What will happen if **YOU** participate in the research?

Participants in this research study will be followed throughout three school years (2022-to-2023, 2023-to-2024, 2024-to-2025).

Data collection periods will be scheduled in coordination with PSJA and La Joya ISD school district staff.

The **First data collection** will be conducted in pre-kindergarten, school year 2022-2023; the **second data collection** in kindergarten, school year 2023-2024; and the **third data collection** in 1<sup>st</sup> grade, school year 2024-2025.

By agreeing to participate, the following data will be collected:

- Participant's profile (one-time collection and yearly cross reference for updates/changes such as child transferring to other schools or withdrawal from school).
- Surveys:
  - Family demographics survey: collected at the beginning of the study.
  - Home Health characteristics survey: collected several times within the three years of the study.

**Data collection Procedures** – The following information and assessments will be collected throughout the three years of the project.

Once a year:

- Child's height and weight to compute, plot and interpret Body Mass Index (BMI).
- School meal observation of served and consumed breakfast and lunch for three consecutive days.
- Child's physical fitness measurement by using the PACER test.

Twice a year:

- Student health knowledge test.

The implementation of the Bienestar SHCP will be for all enrolled students in selected schools, but data collection will **ONLY** include consented students.

### Risks – “What are the risks of participation in the research?”

There are no expected risks associated with the study procedures. All study related documents will be secured and stored by the researchers. Participant profiles will not be shared with any other entity, organization and/or company, unless otherwise stated by Protected Health Information (PHI).

#### **What if a research-related injury occurs?**

The investigators have taken all necessary measures to minimize known or unexpected risks. In the event of a research-related injury or adverse reaction during data collection, schools will seek medical attention immediately, contact the participant's parents and report it to the investigators. Researchers will not be responsible for covering any medical fees, nor issue monetary compensation. See the section “Contact Information” for phone numbers and additional information.

### Benefits – “How could you or others benefit from participating in this study?”

Participants in selected schools will acquire knowledge from the implementation of lessons from the Bienestar Coordinated School Health Program. Also, participants will learn to live healthier lifestyles, which will help them prevent obesity and the development of type 2 diabetes and other associated illnesses. In addition, each year, parents will receive a health report card of their child's results for participating in the study.

### Costs – Will taking part in this study cost anything?

There is no cost involved for participation in this study.

**Confidentiality – How will your records be kept confidential?**

Information collected from participants is confidential within the limits of the law. No participant's personal information that could possibly identify them will be published in a journal or book. However, The Institutional Review Board (IRB) and other groups that have the responsibility of monitoring research may request records which may identify a participant in this study.

**What is Protected Health Information (PHI)?**

STEPS protects your Protected Health Information for any information we collect. This includes questionnaires and demographic data (i.e., age, marital status, employment, education etc.). According to the law, participants have the right to decide who can view their protected health information. Participants, agreeing to this study, automatically grant permission to the investigators and research study staff (individuals hired to carry the study forward) to have access to health information related to this research study.

**How will your PHI be shared?**

Participant's health information will be kept confidential and only be accessible to the members of the research team from UTRGV, the Institutional Review Board, the Compliance Office of UTRGV, and the sponsor of the study (HHSC of Texas). If deciding to participate in this study, participants grant permission to the above groups, to collect, use and share all collected health information.

**How long will your PHI be used?**

By signing this form, the participant allows researchers to use, evaluate and disclose collected information for purposes of this study. The consent expires when all data collection for the study is concluded.

**Contact Information – Who can you contact if you have questions, concerns, comments, or complaints?**

For questions, concerns, comments, complaints, or problems related to this study contact:

Primary contact: (Monday thru Friday 8am to 5pm)

Zasha Romero, Ph.D. at UTRGV office (956) 665-2881 or by email at [zasha.romero@utrgv.edu](mailto:zasha.romero@utrgv.edu)

Secondary contact:

Lin Wang, Ph. D. at UTRGV office (956) 665-5263 or by email at [lin.wang@utrgv.edu](mailto:lin.wang@utrgv.edu)

The UTRGV committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research participant, and/or take any comments or complaints.

UTRGV IRB (956) 665-2093 or by mail to IRB, UTRGV, 1201 University Drive, Edinburg, TX 78539.

ISD: \_\_\_\_\_ School Name: \_\_\_\_\_ Teacher: \_\_\_\_\_

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Independent School Districts Pharr- San Juan- Alamo (PSJAISD) & La Joya (LJISD)

**Research Consent & Authorization Signature Section**

**(Read, sign and return this page to UTRGV STEPS)**

By agreeing to participate in this research study, YOU are agreeing to all the terms and conditions of the study. A copy of this consent form will be provided for your own records. By signing this form, you do not waive any of your legal rights.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read and understood the research study terms and conditions.
- Your questions have been answered to your satisfaction about your participation, data collection and the use of protected health information.

**Signature Section (PARENT, LEGAL GUARDIAN, SURROGATE)**

- You have voluntarily decided to take part in this research study.
- You authorize the data collection, use and sharing of protected health information as described in this form.
- You agree to provide personal information, phone number, email, and home health demographic information.

I, \_\_\_\_\_ grant permission for my child \_\_\_\_\_ to participate  
(Parent / Legal Guardian) (Student Name)

in the STEPS/SNAP -Ed. I also understand that I will be invited to participate, voluntary, in completing a survey for the purpose of the study.

\_\_\_\_\_  
Signature of Parent / Legal Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Parent/Legal Guardian E-mail Address

(\_\_\_\_)\_\_\_\_\_  
Parent/Guardian Phone Number

**STUDENT PROFILE** (this section must be completed by parent/legal guardian or school staff)

**Student Name:** \_\_\_\_\_

**Date of Birth:** \_\_\_\_/\_\_\_\_/\_\_\_\_ **Age** \_\_\_\_

**Student's Gender:** ☐ Male ☐ Female

**Student School ID:** \_\_\_\_\_

**Ethnicity:** ☐ Hispanic/Latino ☐ Non-Hispanic/Non-Latino ☐ Prefer not to respond

**Race:** ☐ White

☐ Black/African American

☐ Asian

☐ Native Hawaiian or Other Pacific Islander

☐ American Indian/Alaska Native

☐ Prefer not to respond

☐ Unknown

☐ Check if consented and authorization obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English. Have witness initial below.

Declaration of witness: I was present for the entire consent process.

\_\_\_\_\_  
(Name of witness).

**UTRGV** Approved: 08/02/2022  
Expires: N/A

*Read, Sign and Return this Page to UTRGV STEPS/SNAP -Ed*