South Texas Early Prevention Studies PreK
Informed Consent Form
September 28, 2018

Note: An new IRB number 18-0415 was assigned from the new admin system from UTRGV

Title of Study:
South Texas Early Prevention Study Pre-K" (STEPS Pre-K)

Consent to be part of the South Texas Prevention Study (STEPS)
To be conducted at:
Pharr-San Juan-Alamo Independent School Districts (PSJAISD)
La Joya Independent School Districts (LJISD)
University of Texas Rio Grande Valley (UTRGV)

Information about this form

If you are providing consent for someone else, for example your child, your next-of-kin or someone for whom you are the legal guardian or are designated as a surrogate decision-maker on a medical power of attorney, please note that in the sections that follow the word "you" refers to the person you are providing consent for.

You may be eligible to take part in a 2-year research study. This form gives you important information about the study.

Please take time to review this information carefully. Please feel free to talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you. Any information included in this form will not be shared with any other agency outside this study.

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

Voluntary Participation – You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) and Co PIs are the researchers directing this study; they are responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Roberto P. Treviño, M.D., with UTRGV Department of Health and Human Performance (DHHP); the Co-PIs are Drs. Lin Wang and Zasha Romero with UTRGV DHHP and Dr. Xiaohui Wang with UTRGV School of Mathematical and Statistical Sciences.

Study Sponsor: U.S. Department of Health and Human Service (DHHS)
DHHS is a federal government agency that promotes scientific research and is funding this study (the sponsor). The sponsor reviewed the study plan and is providing money to UTRGV so that the researchers can conduct the study.

Purpose of this study – "Why is this study being done?"

The researchers are asking you to take part in a 2-year study of a children's obesity prevention program to understand its effectiveness. We believe that a combination of teaching, modeling healthy behaviors, and community support in childhood can reduce the risk of developing obesity. Together, working with school staff from LJISD and PSJAISD, we hope to improve the health of children. We will be asking students, parents, teachers, school administrators, cafeteria staff, and nurses for their thoughts and recommendations on how to improve the Bienestar coordinated school health program.

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This is a research study to evaluate the effectiveness of a school-based obesity prevention program. Bienestar is a health program that combines an instructional portion of health classes, P.E. classes, parent newsletters, communications and cafeteria classes.

Researchers hope to learn about best methods for implementation and how effective the Bienestar is in the schools. Your feedback will help the researchers improve the Bienestar school health program.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you or your child is enrolled in pre-kindergarten at LJISD and PSJAISD.

How many people are expected to take part in this study?
This study will enroll approximately 5068 study participants [2352 children, 2352 parents (1 parent per child) and 364 school staff].

Information about Study Procedures – "What will be done if you decide to be in the research?"

While your child is taking part in this study, we will plan on seeing him/her with his/her class during the school years 2018 – 2019 and 2019 - 2020, at their school: once at the beginning of the year for baseline data collection and then at the end of the school year with post data collection (4 data collection periods). The visits will be scheduled with the school staff of LJISD and PSJAISD.

Study Procedures - as a participant, you will undergo some of the following procedures 4 times:

- We will ask you about your child's medical history.
- We will ask about your demographic information. For example, we will ask for parent educational attainment and/or how many people live in your household.
- We will measure your child's height, and weight. Each measurement will take 5 minutes. We will use your child's height and weight to calculate their body mass index (BMI). Every child will be asked to take off their shoes, socks, and may be asked to adjust their hair so that an accurate height and weight measurement can be obtained.
- We will be recording the meals which your child consumes at school through the use of digital imagery. This will be of breakfast, lunch, and dinner for three days.
- We will send home a parental health practices questionnaire for you to fill out. This questionnaire(s) will take about 30 minutes to complete.
- We will measure physical activity of the child using the PACER test. This test will measure the number of laps your child can do within a certain period of time.
- We will schedule parent face-to-face meeting with parents to check on their child's health progress and to provide you reports on your child's health screenings.
- We will schedule one end-of-the-year meet to evaluate the health program.
- We will collect your child's academic performance from the school records.

All children in your child's grade will receive the health program, even if they choose not to take part in the health exams.

Agreeing to participate in this study also means that you will allow us to contact and speak with you. We will call/text you before we collect data from your child (only four times throughout the study), as a reminder. We will also call/text you to remind you about the parent meetings we will hold. In addition, you will receive a copy

of your child's results. Finally, we will also speak with you to answer any questions that you might have about our research or the study.

Risks – "What are the risks of participation in the research?"

There are no reasonably expected risks associated with the study procedures. To protect your child's privacy, physical measurements are taken behind a screen with clothing on. All study related documents will be stored by the study team in a secure location and nobody outside of the research team will have access to the information collected as part of this study.

For more information about risks, ask one of the researchers or study staff.

Are there Risks related to withdrawing from the study?
If you decide to withdraw from this study early, please discuss your decision with the Co-Investigator, Dr. Zasha Romero. The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit includes completion of forms stating your withdrawal. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

What if a research-related injury occurs?
The investigators have taken the necessary measures to minimize known or expected risks. Nonetheless, you may experience some secondary problems or risks even if the investigators have carefully tried to prevent them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your doctor and the investigators. See the section "Contact Information" for phone numbers and additional information.

If you are injured or made sick from taking part in this research study, we will contact the parents immediately. You will be responsible for any cost. We have no plans to give you money if you are injured.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

You may not receive any personal benefits from being in this study. However, with the gained knowledge from the Bienestar Coordinated Health Program, you may be able to lead a healthier lifestyle and be aware of risks associated with obesity and type 2 diabetes.

If we find out that your child is at risk for diabetes or obesity we will inform you immediately. We will provide you with a health report card that will inform you of your child's results.

We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

All children attending the LJISD and PSJAISD and who participate in the program will benefit from the education received. Only children that are consented will take part in data collections.

Payments – Will there be any payments for participation?

There are no payments for your participation.

Costs – Will taking part in this study cost anything?

You will not have to pay any money to take part in this study.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

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

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Zasha Romero, Ph.D. can be reached at (956) 665-2881 or zasha.romero@utrgv.edu.

If primary is not available or it is after normal work hours, contact:
Lin Wang, Ph. D. at (956) 665-5263 or 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 subject, and take any comments or complaints you may wish to offer. You can contact the IRB by calling (956) 665-2093 or by mail to IRB, UTRGV, 1201 University Drive, Edinburg, TX 78539.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.

Adult Signature Section

- You have voluntarily decided to take part in this research study.
- You authorize the collection, use and sharing of your protected health information as described in this form.

Printed Name of Subject	Signature of Subject	Date	Time
× × × × ×	× × × × × ×	× × ×	× × AM PM

Printed Name of Witness	Signature of Witness	Date	Time
× × × × ×	× × × × × ×	× × ×	× × AM PM

☒ *Check if consent 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. × ←(initials of witness)

Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent and Authorization	Date	Time
× × × × ×	× × × × ×	× ×	× × AM PM

☒ Consent and authorization was obtained from this individual who is unable to read and/or write but can otherwise communicate and/or comprehend English. The method used for communication with the subject was: × × ×.
The specific means by which the subject communicated agreement to participate was:
× × × × × × × × ×

The University of Texas Rio Grande Valley
IRB APPROVED
IRB# 2017-175-07
Expires: 03/26/2019

IRB APPROVED UTRGV

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Surrogate Signature Section

- You are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You also authorize the collection, use and sharing of another person's protected health information as described in this form.

Printed Name of Subject	Signature of **Subject**, indicating Assent *(If incapable of signing, person obtaining consent should initial here)*	Date	Time AM PM
Printed Name of Person Giving Consent & Authorization for Subject	Signature of Person Giving Consent & Authorization ☐Parent/☐Guardian/☐Legally Authorized Representative	Date	Time AM PM
Printed Name of Witness	Witness Signature	Date	Time AM PM
Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent & Authorization	Date	Time AM PM

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