

**Official Title: Preventing Non-communicable Diseases in Guatemala  
Through Sugary Drink Reduction**

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University of Pennsylvania  
Informed Consent Form

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**Title of the Research Study:** Preventing non-communicable diseases in Guatemala

**Protocol Number:**

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You are being asked to take part in a research study. This is not a form of treatment or therapy. It is not supposed to detect a disease or find something wrong. Your decision regarding participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if you decide to allow your child to participate.

If you do not understand what you are reading, please use the contact information listed at the end of this document to have a member of our team explain anything you do not understand, including any language contained in this form. If you decide to participate, you do not need to take any action. If you decide not to participate, please use the contact information provided to speak with a member of the research team to inform them that you do not want your child to participate. Keep this form, in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

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**What is the purpose of the study?**

The purpose of the study is to learn more about adolescent's attitudes towards nutrition information on food and beverage packaging.

**Why was I asked to participate in the study?**

Your child is being asked to join this study because the school that he or she is enrolled in has agreed to participate in this study. Because your child is between the ages of 12 and 18 years old, he or she qualifies to participate in the study. However, because he or she is not an adult, we are asking for your permission to allow your child to participate.

**How long will I be in the study?**

The study will take place over a period of six weeks. If your child has permission to participate in the study, during the next six weeks we will ask him or her to complete a survey only once. The survey will take between 5 and 10 minutes to complete.

## APPENDIX A –INFORMED CONSENT FORM

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**Where will the study take place?**

The survey will take place at the store inside of your child's school.

**What will I be asked to do?**

We are asking you to provide your permission for your child to participate in this study. Only after your child has made a purchase in the school store, will we ask your child to complete a survey about their shopping experience and to answer some questions about themselves, such as their age and grade level. The surveys will be conducted during school hours and should not interfere with primary instructional hours. During the survey we will not ask for your child's name and his or her responses will be recorded by a trained research assistant. After the survey, your child will be given a prize for their participation.

**What are the risks?**

There are no risks from participating in the study. Some of the questions may make your child uncomfortable, and if they do, your child does not have to answer them.

**How will I benefit from the study?**

There is no direct benefit to you or your child. However, your participation could help us understand how to address childhood obesity in school environments, which can benefit you indirectly.

**What other choices do I have?**

Your child's alternative to being in the study is to not be in the study.

**What happens if I do not choose to join the research study?**

You may choose to give permission to your child to join the study or you may choose not to allow your child to join the study. Your participation is voluntary.

There is no penalty if you choose not to give permission to your child to join the research study. You and your child will lose no benefits or advantages that are now coming to you, or would come to you in the future. Your therapist, social worker, nurse, doctor or school staff will not be upset with your decision.

If you are currently receiving services and you choose not to volunteer in the research study, your services will continue. If you choose not to be in the study, it will not affect your child's grades or your relations with your child's school

**When is the study over? Can I leave the study before it ends?**

The study is expected to end after all participants have completed all information has been collected. The study may be stopped without your consent for the following reasons:

- The PI feels it is best for your safety and/or health-you will be informed of the reasons why.
- You have not followed the study instructions
- The PI, the sponsor or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime

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If you change your mind and do not want your child to participate, you have the right to do so. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so.

If you no longer wish to be in the research study, please contact Dr. Joaquin Barnoya, at INCAN and inform Violeta Chacon or a member of her team that your child does not have permission to participate in the study.

Your child's name will not be added to a list of students who are able to participate. This list will be consulted before administering each survey to make sure every child that participates has permission to do so.

**How will confidentiality be maintained and my privacy be protected?**

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your child's name will not be used.

Your child's records and data generated by the study may be reviewed by members of the research team at INCAN and The University of Pennsylvania to assure proper conduct of the study and compliance with regulations. The results of this study may be published. If any data is published, you and your child will not be identified by name.

During the interview process, your child's name will not be recorded. Your child's responses will be recorded on paper and the hand written copy will be kept in a locked filing cabinet. The only people who will have access to your child's information are the study investigators and the study staff.

**Will I have to pay for anything?**

The cost of the item that your child purchases at the school store will be the only cost associated with participating in this study.

**Will I be paid for being in this study?**

You and your child will not be financially compensated for participating in this study. However, your child will be given a small prize for their participation.

**Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?**

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your child's rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

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Additionally, you may also contact the Office of Regulatory Affairs at INCAN with any questions, concerns or complains by calling 502 2417 2100.

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By taking no further action, you are granting your child permission to take part in this research study. If you have any questions or there is something you do not understand, please ask.