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

NCT number: NCT04022694

Document name: Protocol – Warning Label Aim

Document date: November 6, 2017

Protocol Details

Basic Info

Confirmation Number:	**cfbfjijj**
Protocol Number:	
Created By:	**WOOD, MAKENZIE H**
Principal Investigator:	**ROBERTO, CHRISTINA**
Protocol Title:	**Preventing non-communicable diseases in Guatemala through sugary drink reduction**
Short Title:	**Preventing non-communicable diseases in Guatemala**
Protocol Description:	**Guatemala is a lower middle income country with a rising prevalence of overweight and obesity. Because consumption of sugary drinks is strongly associated with obesity, policy makers are interested in strategies to reduce consumption. The proposed research will evaluate the impact of different types of sugary drink warning labels on adolescents purchases in Guatemalan schools**
Submission Type:	**Social and Biological Sciences**
Application Type:	**EXPEDITED Category 7**

Resubmission*
No

Study Personnel

Principal Investigator

Name:	**ROBERTO, CHRISTINA**
Dept / School / Div:	**10599 - ME-Division of Health Policy**
Campus Address Mail Code	**6021**
Address:	**1110 BLOCKLEY HALL** **423 GUARDIAN DR**
City State Zip:	**PHILADELPHIA PA 19104-6021**
Phone:	**215-573-9718**
Fax:	**215-573-8779**
Pager:	
Email:	**croberto@mail.med.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**01/02/2019**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Study Contacts

Name:	**WOOD, MAKENZIE H**
Dept / School / Div:	**10599 - ME-Division of Health Policy**
Campus Address Mail Code	**6021**
Address:	**BLOCKLEY HALL** **423 GUARDIAN DR**
City State Zip:	**PHILADELPHIA PA 19104-6021**
Phone:	**215-573-9179**
Fax:	
Pager:	
Email:	**makwood@gse.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**05/23/2020**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**HUA, SOPHIA V**
Dept / School / Div:	**10599 - ME-Division of Health Policy**
Campus Address Mail Code	**6021**
Address:	**BLOCKLEY HALL** **423 GUARDIAN DR**
City State Zip:	**PHILADELPHIA PA 19104-6021**
Phone:	
Fax:	
Pager:	
Email:	**sohua@mail.med.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**07/17/2019**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**PETERHANS, ANA P**
Dept / School / Div:	**10599 - ME-Division of Health Policy**
Campus Address Mail Code	**6021**
Address:	**BLOCKLEY HALL** **423 GUARDIAN DR**
City State Zip:	**PHILADELPHIA PA 19104-6021**
Phone:	**215-573-9718**
Fax:	**-**
Pager:	
Email:	**anapeter@mail.med.upenn.edu**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed :	

Other Investigator

None

Responsible Org (Department/School/Division):

10599 - ME-Division of Health Policy

Key Study Personnel

None

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?
No

Penn Intellectual Property*
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania?
No

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

Social and Biological Sciences

Study Instruments
Discuss the particulars of the research instruments, questionnaires and other evaluation instruments in detail. Provide validation documentation and or procedures to be used to validate instruments. For well know and generally accepted test instruments the detail here can be brief. More detail may be required for a novel or new instrument. For ethnographic studies identify any study instruments to be used (i.e. for deception studies) and describe in detail where, when and how the study will be conducted and who or what are the subjects of study. Note: For more information on how to conduct ethical and valid ethnographic research, follow the link For oral histories or interviews provide the general framework for questioning and means of data collection. If interviews or groups settings are to be audio taped or video taped describe in detail the conditions under which it will take place. Include a copy of any novel or new test instruments with the IRB submission.
We describe all study measures in detail in the study design and procedures sections below and they appear in our appendices. Below is a brief summary of assessments. Purchasing Survey: After obtaining permission from caregivers, a survey will be administered to students after they have made a food or beverage purchase at a school store. The survey will assess participants nutrition knowledge and label awareness, recall, and use, and trust in label information. Frequency of school store visits and sociodemographic characteristics (e.g., age, sex, race/ethnicity, grade level, and height and weight) will also be assessed (see Appendix B for survey). Beverage Frequency Questionnaire: Participants will also complete a beverage frequency questionnaire to assess their consumption of different types of beverages. This questionnaire will be based on the BEVQ-15, a survey instrument that has been validated as an effective tool used to capture changes in beverage consumption. (1-4) (see Appendix E for BEVQ-15). For each beverage category, the questionnaire assesses frequency of consumption and volume typically consumed. (see Appendix D for adapted questionnaire).

Group Modifications
Describe necessary changes that will or have been made to the study instruments for different groups.

None of the survey questionnaires will differ across randomly assigned groups. Regarding the schools that will be enrolled in the study, pairs of matched private/public schools will be randomized to 1 of 3 labeling conditions

Method for Assigning Subjects to Groups

Describe how subjects will be randomized to groups.

Individual participants will not be randomly assigned to groups. Instead, randomization will occur at the school level. Nine schools will be participating in this research and randomization will be stratified based on whether a school is public (n = 6) or private (n = 3). The Penn research team will use a random number generator to randomize schools to one of three labeling conditions, and the Guatemala team will implement the labels based on the randomization assignment.

Administration of Surveys and/or Process

Describe the approximate time and frequency for administering surveys and/or evaluations. For surveys, questionnaires and evaluations presented to groups and in settings such as high schools, focus group sessions or community treatment centers explain how the process will be administered and who will oversee the process. For instance, discuss the potential issues of having teachers and other school personnel administer instruments to minors who are students especially if the content is sensitive in nature. Describe the procedure for audio and videotaping individual interviews and/or focus groups and the storage of the tapes. For instance, if audio tape recording is to be used in a classroom setting, describe how this will be managed if individuals in the class are not participating in the study. Explain if the research involves the review of records (including public databases or registries) with identifiable private information. If so, describe the type of information gathered from the records and if identifiers will be collected and retained with the data after it is retrieved. Describe the kinds of identifiers to be obtained, (i.e. names, social security numbers) and how long the identifiers will be retained and justification for use.

Students and their caregivers will first be contacted about study participation using a permission letter (see Appendix A) sent either as a printed letter or electronically. The letter will explain that their children may be asked to complete a short survey after making a purchase at the school store. Caregivers who wish to refuse participation can call a number provided in the permission letter. A list will be maintained with the names of students who have permission to participate. Research assistants will consult this list before administering any surveys to ensure the student has permission to participate. Adolescents who consent to participate and have made a purchase from the school store will be given the opportunity to complete a short survey; verbal assent must be obtained prior to enrollment. Research assistants will be stationed at the school stores during the heaviest traffic times (between 10:00am and 1:30pm and 2:30pm and 3:30pm) Monday to Friday and will invite adolescents to participate in the survey after they make a food and/or beverage purchase at the school store. Research assistants will record the item purchased (type of food/beverage) along with brand, quantity, size, and price. In addition, we will administer a survey that includes a validated beverage frequency questionnaire to assess typical beverage intake (Appendix B). Research assistants will also record the number of students who refuse participation along with their gender. The survey is estimated to last approximately 5-10 minutes. Participants will only be eligible to take the survey once.

Data Management

Describe how and who manages confidential data, including how and where it will be stored and analyzed. For instance, describe if paper or electronic report forms will be used, how corrections to the report form will be made, how data will be entered into any database, and the person(s) responsible for creating and maintaining the research database. Describe the use of pseudonyms, code numbers and how listing of such identifiers will be kept separate from the research data.

We will only use participant identification numbers for data linkage purposes; we will not collect any participant names on the research questionnaires. The study identification number, and no other identifying information, will be used on all data collection instruments. All study staff will be reminded to appreciate the confidential nature of the data collected and contained in these databases. Only the researchers involved in this study and those responsible for research oversight will have access to the identifiable information provided. Risk of loss of confidentiality will be minimized by storing surveys in locked file cabinets in locked offices accessible only to trained study staff. The surveys will be administered on paper and will not contain any identifying data. All completed surveys will be stored in a locked file cabinet in the secure office of the INCAN team. Electronic data will be stored on secure, password-protected firewalled servers at INCAN in Guatemala and at UPENN. Only trained study staff will have access to the passwords used to access the databases. Data will be transferred from Guatemala

to Penn via PennBox, a secure folder for data storage.

Radiation Exposure*
Are research subjects receiving any radiation exposure (e.g. X-rays, CT, Fluoroscopy, DEXA, pQCT, FDG, Tc-99m, etc.) that they would not receive if they were not enrolled in this protocol?
No

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?
No

CACTIS and CT Studies*
Does the research involve Center for Advanced Computed Tomography Imaging Services (CACTIS) and CT studies that research subjects would not receive if they were not part of this protocol?
No

CAMRIS and MRI Studies*
Does the research involve Center for Advanced Magnetic Resonance Imaging and Spectroscopy (CAMRIS) and MRI studies that research subjects would not receive if they were not part of this protocol?
No

Cancer Related research not being conducted by an NCI cooperative group*
Does this protocol involve cancer-related studies in any of the following categories?
No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
No

CTRC Resources*
Does the research involve CTRC resources?
No

If the answer is YES, indicate which items is is provided with this submission:

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
No

Primary Focus*
Sociobehavioral (i.e. observational or interventional)

Protocol Interventions

	Sociobehavioral (i.e. cognitive or behavioral therapy)
	Drug
	Device - therapeutic
	Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
	Surgical
	Diagnostic test/procedure (research-related diagnostic test or procedure)
	Obtaining human tissue for basic research or biospecimen bank
x	**Survey instrument**
	None of the above

The following documents are currently attached to this item:

There are no documents attached for this item.

Sponsors

Business Administrator

Name:	**KENNEDY-SMITH, NANCY J**
Dept / School / Div:	**10599 - ME-Division of Health Policy**
Phone:	**215-573-2769**
Fax:	**215-573-8778**
Pager:	
Email:	**KENNEDYN@MAIL.MED.UPENN.EDU**

Department budget code

400 - 400 - 4 - 572942 - 5348 - 2446 - 4176

Funding Sponsors

Name:	**FOGARTY INTERNATIONAL CENTER/NIH/DHHS**
Type:	**UPENN Federal**

Funding sponsors billing address
If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.

Funding sponsors gift
Is this research being funded by a philanthropic gift?
No

Regulatory Sponsor

IND Sponsor

none

400 - 400 - 4 - 572942 - 5348 - 2446 - 4176

Industry Sponsor

None

Project Funding*
Is this project funded by or associated with a grant or contract?
Yes

Selected Proposals

Proposal No	Title
10061549	**Preventing non-communicable diseases in Guatemala through sugary drink reduction and capacity bui**

Sponsor Funding
Is this study funded by an industry sponsor?
No

Status of contract

The following documents are currently attached to this item:

Grant Application (roberto-ssbwarninglabelsguatemalar21-final.docx)

Multi-Site Research

Other Sites

No other sites

Management of Information for Multi-Center Research
As co-principal investigators, Drs. Roberto and Barnoya will meet by Skype conference calls weekly to assess the interim results and the coordination of any modifications to the protocol. In the event that any unanticipated problems involving risk to participants or others occurs, the co-principal investigators will communicate immediately to effectively address and manage these risks. Throughout the study a reliable and effective channel of communication will be upheld between both teams at INCAN and The University of Pennsylvania. There will be data and safety monitoring meetings every 6 months to more specifically assess the data quality, participant recruitment, accrual and retention, participant risk versus benefit, and study outcomes. The research team will also correspond by email and telephone as needed. Only the researchers involved in these studies and those responsible for research oversight will have access to the identifiable information provided. In addition, the data collected as part of this study will not contain identifying information, which will therefore pose minimal risk to its participants.

The following documents are currently attached to this item:

There are no documents attached for this item.

Protocol

Abstract
Guatemala is a lower middle income country struggling with the double-burden of disease (malnutrition and obesity coexisting). Consumption of sugary drinks is strongly associated with obesity and related health problems. Food labeling has become a popular policy approach to address high levels of sugary drink intake. Some countries are interested in placing health warning labels on sugary drinks, but there are no real-world studies testing the effects of such labels. The aim of the proposed research is to test the effect of repeated exposure to warning labels on mean fluid ounces of sugary drinks purchased by adolescents in Guatemala. We define a sugary drink as any non-alcoholic beverage that lists any form of caloric sugar-based sweetener as an ingredient (this would not include 100% juice). We will enroll nine schools in the study (three private and six public). Each group of matched private/public schools will be randomized to 1 of 3 labeling conditions. In this six-week study, we will collect sales data during two weeks without labels, two weeks when labels are displayed, and two weeks after labels have been removed. We will also conduct surveys with 1500 students.

Objectives

Overall objectives
The objective of this study is to conduct one of the first field experiments to assess the degree to which sugary drink warning labels encourage adolescents to reduce their intake in a country that does not yet have any front-of-package food labeling regulations. We will also evaluate whether a graphic-based warning label is more effective compared to a text-based warning label.

Primary outcome variable(s)
The primary outcome will be mean ounces of sugary beverages purchased based on sales data, which will include the date of the transaction and the type of food or beverage sold (e.g., diet soda, lemonade) along with the item brand, size, quantity, and price.

Secondary outcome variable(s)
Our secondary outcomes will be the total kilocalories (kcals) purchased at the school store based on the surveys we collect. A measure of total calories purchased will allow us to assess whether adolescents who buy fewer sugary drinks compensate by buying other snack foods. We define a sugary drink as any non-alcoholic beverage that lists any form of caloric sugar-based sweetener as an ingredient (this would not include 100% juice). We will also record the presence and type of food/beverage marketing in the store.

Background
Overweight and obesity are estimated to account for 3.4 million deaths worldwide annually. (5) Although the prevalence of obesity in high-income countries is more than double that of low- or middle- income countries, the increase has been the fastest among those nations. (5) Guatemala is a lower middle income country struggling with the double-burden of disease (malnutrition and obesity coexisting). It has the second highest prevalence of childhood stunting in the world (49%) and a rising prevalence of overweight and obesity, particularly among women (49%). (6) This is concerning because obesity is a risk factor for numerous health problems, including type 2 diabetes, cardiovascular disease, and at least 13 different cancers. (7-12) Cancer is the third leading cause of mortality in Guatemala. (13) Most of the population (75%) lives below the poverty line (14) and Guatemala is one of the most unequal countries in the world. (15) These staggering statistics highlight the tremendous need for non-communicable disease (NCD) research and capacity building in Guatemala. Consumption of sugary drinks is strongly associated with obesity and related health problems. (16-21) Global strategies to reduce sugary drink intake have been identified by the World Health Organization as a key need. (22) In Guatemala, sales of sugary drinks have increased 25% in the last decade (101 liters per capita) (23-24) and Guatemalas per capita intake is one of the highest worldwide (mean is 2.69 servings per day, higher than Mexico (2.40) and the United States (U.S.) (1.89)). (25) Food labeling is a policy approach gaining traction to encourage healthy choices. Over 20 countries have implemented mandatory or voluntary front-of-package or shelf tag nutrition labeling systems. (26) Chile has required health warning labels on packaged foods to alert consumers to high levels of certain nutrients. (27) Several U.S. states and cities have introduced bills to place warning labels on sugary drink containers or advertisements. (28-31) In 2011, Guatemala approved a regulation requiring a nutrition label (similar to the U.S. Nutrition Facts Label) on food packaging. However, the limited research on this label has found that only 27% of low socioeconomic status (SES) Guatemalan women report using the label and 78% have limited health literacy. (32) The label being difficult to understand is the main reason reported for not using it. (32) For these reasons, multiple organizations including the Panamerican Health Organization (PAHO), (33) Central American Council of Ministries of Health, (34) and the Guatemalan National Commission of NCDs (35) have published reports recommending a uniform, easy-to-understand front-of-package labeling system. Therefore, our proposed research testing different labels will provide timely data to inform these policy discussions. Significant contributions of the proposed research. We expect the proposed study to provide the first data on the impact of different types of sugary drink warning labels on adolescents purchases.

Study Design

Phase*
Not applicable

Design
This study will examine how repeated exposure to sugary drink warning labels influences total sales of sugary drinks over time as well as sugary drink purchases among 1500 adolescents. School Recruitment: We will recruit nine schools to participate in this study. Three of the enrolled schools will be private (average tuition fees in private schools are $223.50 per month) and six will be public (free). Within private and public schools, we expect student body demographics to be similar based on income, age, and gender, respectively. Student Recruitment: Students and their corresponding caregivers will be recruited using an active-information, passive-consent permission process, which we have used for other research school-based studies in Guatemala. (36-41) Students between the ages of 12-18 and who

have shopped at one of the participating stores will qualify to participate. We will use the communication channel each school prefers (e.g., e-mail, printed letters sent home with students) to send permission letters to caregivers (see Appendix A). The letters will explain that their children may be asked to complete a short survey after making a purchase at the school store. Caregivers who wish to refuse participation can call a number provided in the permission letter. All students whose caregivers did not withdraw will be eligible to participate in the survey. Permission letters will be sent two weeks before data collection. Adolescents who have made a purchase from the school store will be asked if they want to complete a short survey; verbal assent must be obtained prior to enrollment (see Appendix C for oral consent script). School Store Setting: Nine schools will be participating in this research and randomization will be stratified based on whether a school is public (n = 6) or private (n = 3). The Penn research team will use a random number generator to randomize schools and the Guatemala team will implement the labels based on the randomization assignment. Each pair of matched private/public schools will be randomized to 1 of 3 labeling conditions: 1) calorie label (control); 2) text warning labels; or 3) graphic warning labels displaying amounts of sugar (see Appendix F).The warning label language will be translated into Spanish before the labels are implemented in the school stores. In this six-week study, we will receive purchasing data from the schools during two weeks without labels, two weeks when labels are displayed, and two weeks after labels have been removed Warning Label Survey: During the intervention weeks, we will survey approximately 1500 adolescents after they have made a purchase at the school store. We will stratify recruitment to ensure approximately half of the 1500 surveyed students (n=750) are enrolled in public school and half (n=750) are enrolled in private school. Adolescents will be asked if they want to participate in a short, 5-10 minute survey. They will be offered a small prize (e.g., school supplies like pens or pencils) as a token of appreciation. The survey will include constructs that map onto our conceptual model of label effects, such as nutritional knowledge, label awareness, and trust of information on nutritional labels (see Appendix B for survey questions). We will also administer a beverage intake questionnaire (see Appendix D). This questionnaire has been validated among children and adolescents (42,43) Demographic Information: During the survey, we will ask participants to provide basic demographic information including age, sex, race/ethnicity, grade level, and height and weight (see Appendix B for demographic questions). Sales Data: We will collect sales data by setting up a point of sale system in each school store. This system will allow us to collect sales data from each store that will include a row for each purchase made at the school store, including the date of the transaction and the type of food or beverage sold (e.g., diet soda, lemonade) along with the item brand, size, quantity, and price. We will also record the presence and type of food/beverage marketing in the store.

Study duration
We anticipate it will take the entirety of the six week data collection period to survey all 1500 adolescents. It will take 5-10 minutes for each participant to complete the survey. We aim to implement the warning labels in school stores by May 2018 and will complete the data collection by the end of June 2018.

Resources necessary for human research protection
Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.

Characteristics of the Study Population

Target population
To be eligible for the survey component of this project, participants must be: 1) Between 12-18 years or older; 2) Be a currently enrolled student at one of the enrolled schools 3) Have made a purchase at the school store.

Subjects enrolled by Penn Researchers
0

Subjects enrolled by Collaborating Researchers
1500

Accrual
The schools participating in this study will enable us to easily recruit students shopping at the school stores. With a sample size of 1500 (500 per labeling condition), this study is powered to detect small mean differences between the conditions. Specifically, if all three conditions differ by only .21 standard deviations, there is an 82% chance that we would find all differences to be significant.

Key inclusion criteria
To be eligible for the survey component of this project, participants must be: 1) Between 12-18 years or older; 2) Be a currently enrolled student at one of the enrolled schools 3) Have made a purchase at the school store.

Key exclusion criteria
Individuals not meeting the inclusion criteria above will be excluded. Those who will not or cannot give assent will also be excluded from the study. No one will be excluded on the basis of sex or race

Vulnerable Populations

x **Children Form**

Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form

Fetuses and/or Neonates Form

Prisoners Form

Other

None of the above populations are included in the research study

The following documents are currently attached to this item:

Vulnerable Populations (inclusionofchildren.doc)

Populations vulnerable to undue influence or coercion
In addition to the safeguards that will be put in place to ensure adolescents participate in the study free from coercion, no results will be reported in a personally identifiable manner to further protect the identity of each participant.

Subject recruitment
School Recruitment: Nine schools will be participating in this research and randomization will be stratified based on whether a school is public (n = 6) or private (n = 3). The Penn research team will use a random number generator to randomize schools and the Guatemala team will implement the labels based on the randomization assignment. Student Recruitment: Students and their corresponding caregivers will be recruited using an active-information, passive-consent permission process, which we have used for other research school-based studies in Guatemala. Students between the ages of 12-18 and who have shopped at one of the participating stores will qualify to participate. We will use the communication channel each school prefers (e.g., e-mail, printed letters sent home with students) to send permission letters to caregivers (see Appendix A). The letters will explain that their children may be asked to complete a short survey after making a purchase at the school store. Caregivers who wish to refuse participation can call a number provided in the permission letter. All students whose caregivers did not withdraw will be eligible to participate in the survey. Permission letters will be sent two weeks before data collection. Adolescents who have made a purchase from the school store will be asked if they want to complete a short survey; verbal assent must be obtained prior to enrollment.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

Subjects will not be financially compensated for their participation. However, students will be offered a small prize (e.g., school supplies like pens or pencils) as a token of appreciation for their participation.

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
Research assistants will be stationed at the school stores during the heaviest traffic times (between 10:00am and 1:30pm and 2:30pm and 3:30pm) Monday to Friday and will invite adolescents to participate in the survey after they make a purchase at the school stores. Only after confirming that a student has permission to participate will the survey be administered. They will be offered a small prize (e.g., school supplies like pens or pencils) as a token of appreciation. After the adolescent has provided verbal consent, a research assistant will record the item(s) purchased (type of food/beverage) along with brand, quantity, size, and price. We will also assess frequency of school store visits and sociodemographic characteristics (e.g., age, sex, race/ethnicity, grade level, and height and weight). We will recruit 1500 students (between 12 and 18 years old) to answer a brief 5-10 minute survey after making a purchase at the school store. Nine schools will be participating in this research and randomization will be stratified based on whether a school is public (n = 6) or private (n = 3). The Penn research team will use a random number generator to randomize schools and the Guatemala team will implement the labels based on the randomization assignment (see Appendix F for label designs). In this six-week study, we will receive purchasing data from the schools during two weeks without labels, two weeks when labels are displayed, and two weeks after labels have been removed. Studying purchases after the labels have been removed will enable us to understand whether the labels are educating children over time or whether they primarily alter behavior by being a salient reminder at the point of purchase.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
No

Analysis Plan
Data will be descriptively summarized and evaluated for quality prior to the evaluation of primary and secondary endpoints. Means and standard deviations will be used to characterize the primary outcome variable of volume in fluid ounces of sugary drinks purchased. We define a sugary drink as any non-alcoholic beverage that lists any form of caloric sugar-based sweetener as an ingredient (this would not

include 100% juice). Frequencies and percentages will be 50 used to describe categorical variables such as percent of students purchasing a sugary drink. Medians and interquartile ranges will be reported for continuous variables that exhibit skewness. Data will be descriptively summarized overall and by labeling strategy. All outcomes will be analyzed at the purchase level. The mean volume of sugary drinks at each two-week period will be modeled among the calorie label, text label, and graphic label arms by a linear regression model including intervention arm, two-week period, interactions of period and intervention arm and type of school (private or public) as independent variables. We will conduct exploratory analyses to examine whether usual frequency of sugary drink intake (high versus low) and biological sex moderate label effects. Examining only aggregate sales data could lead to incorrect inferences. Therefore, complementary individual-level survey data on purchases will also be collected. This aggregate/individual-level data combination will improve inferences about label effects. Although stratification by school type guarantees this variable will be balanced across our intervention arms, we are including it as a covariate in the model because it will enhance the precision of estimating intervention effects, as it explains variability in the outcome. The effectiveness of the interventions will be tested by evaluating the null hypothesis that the coefficients of the interactions of period and intervention are 0, indicating no change in the difference in volume of sugary beverages purchased across intervention arms from baseline. To account for clustering of purchases within schools, test statistics will be corrected using the variance inflation factor (VIF) as determined by the estimated intraclass correlation coefficient (ICC) for within school correlation. Primary and secondary outcomes in the calorie, text-based warning label, and graphic warning label arms will each be compared to one another. A Bonferroni-holm correction will be applied to control for multiple comparisons. We do not expect substantial missing data due to the point-of-sale technology we are using. The primary analysis will examine changes in labeled (sugary) and non-labeled beverages. Secondary analyses will examine changes for the following specific beverage categories: sugar-sweetened cola, sugar-sweetened sports drinks, sugar-sweetened lemonades/iced teas/juices, artificially-sweetened drinks (e.g., Diet Coke), milk, 100% fruit juice, unsweetened coffee/tea, and bottled water. For the survey data, we will conduct similar linear regression analyzes to compare total mean kcals purchased among intervention arms.

The following documents are currently attached to this item:

There are no documents attached for this item.

Are you conducting research outside of the United States?
Yes

Does your research involve contact with blood or other bodily fluids?
No

Data confidentiality

- x **Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.**
- x **Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.**

  Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.
- x **Wherever feasible, identifiers will be removed from study-related information.**

  A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.

  A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)

  Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.

  Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.

Subject Confidentiality

We will only use participant identification numbers for data linkage purposes. The study identification number, and no other identifying information, will be used on all data collection instruments. Data for the surveys will not contain personal identifying information. Instead, participants will be assigned a random number as an identifier. All study staff will be reminded to appreciate the confidential nature of the data collected and contained in these databases. Only the researchers involved in this study and those responsible for research oversight will have access to the identifiable information provided. Risk of loss of confidentiality will be minimized by storing surveys in locked file cabinets in locked offices accessible only to trained study staff. Electronic data will be stored on secure, password-protected firewalled servers at INCAN in Guatemala and at UPENN. Only trained study staff will have access to the passwords used to access the databases. Data will be transferred from Guatemala to Penn via PennBox a secure folder for data storage.

Sensitive Research Information*

Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?

No

Subject Privacy

Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings in which an individual will be interacting with an investigator. The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).

The privacy of the subjects will not be infringed upon beyond a minimal degree. Participants will be identified based upon their enrollment in one of the six enrolled schools and their age (between the ages of 12-18 years old). Participants and their corresponding caregivers will be contacted for recruitment via permission letters that will be sent either electronically or as printed letters through the mail. Caregivers who wish to refuse participation can call a number provided in the permission letter and the student will no longer be eligible to participate. A list will be maintained with the names of students who have permission to participate. Research assistants will consult this list before administering any surveys to ensure the student has permission to participate Eligible participants will interact with a researcher while completing the survey only after they make a purchase at the school store and give verbal assent to complete the survey. The interaction will take place at the participants school. Participants will be assigned a random number as an identifier to further protect their privacy.

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
The data will be disclosed to research assistants who will receive adequate training to help ensure data confidentiality and subject privacy is upheld.

*Data Protection**

	Name
	Street address, city, county, precinct, zip code, and equivalent geocodes
	All elements of dates (except year) for dates directly related to an individual and all ages over 89
	Telephone and fax number
	Electronic mail addresses
	Social security numbers
	Medical record numbers
	Health plan ID numbers
	Account numbers
	Certificate/license numbers
	Vehicle identifiers and serial numbers, including license plate numbers
	Device identifiers/serial numbers
	Web addresses (URLs)
	Internet IP addresses
	Biometric identifiers, incl. finger and voice prints
	Full face photographic images and any comparable images
	Any other unique identifying number, characteristic, or code
x	**None**

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Tissue Specimens Obtained as Part of Research*
Are Tissue Specimens being obtained for research?
No

Tissue Specimens - Collected during regular care*
Will tissue specimens be collected during regulator clinical care (for treatment or diagnosis)?
No

Tissue Specimens - otherwise discarded*
Would specimens otherwise be discarded?
No

Tissue Specimens - publicly available*
Will tissue specimens be publicly available?
No

Tissue Specimens - Collected as part of research protocol*
Will tissue specimens be collected as part of the research protocol?
No

Tissue Specimens - Banking of blood, tissue etc. for future use*
Does research involve banking of blood, tissue, etc. for future use?
No

Genetic testing
If genetic testing is involved, describe the nature of the tests, including if the testing is predicative or exploratory in nature. If predictive, please describe plan for disclosing results to subjects and provision of genetic counseling. Describe how subject confidentiality will be protected Note: If no genetic testing is to be obtained, write: "Not applicable."
Not applicable.

Consent

1. Consent Process

Overview
Students and their corresponding caregivers will be recruited using an active-information, passive-consent permission process. In this approach, we will use the communication channel each school prefers (e.g., e-mail, printed letters sent home with students) to send permission letters to caregivers. The letters will explain that their children may be asked to complete a short survey after purchasing food or beverage at the school store. Caregivers who wish to refuse participation can call a number provided in the permission letter. All students whose caregivers did not withdraw will be eligible to participate in the survey. Permission letters will be sent two weeks before data collection. Adolescents who have made a purchase from the school store will be asked if they want to complete a short survey. All adolescent participants will provide informed assent prior to participating in the survey (see Appendix C for oral consent script). At any time during the consent process or during the data collection, students will be allowed to decline participating or withdraw from the study. Study enrollment will include a description of the voluntary nature of participation, the study procedures, risks and potential benefits. Adolescent participants will be told that they do not have to answer any questions if they do not wish and can drop out of the study at any time, without any penalty or loss of benefits to which they are otherwise entitled. They will be told that they may not benefit directly from the study and that all information will be kept strictly confidential, except as required by law. All of this language will be tailored to adolescents.

Children and Adolescents
Please see above overview of consent process for description of consent process including parental permission and subject assent.

Adult Subjects Not Competent to Give Consent
All adult subjects will be competent to give informed consent.

2. Waiver of Consent

Waiver or Alteration of Informed Consent*
No Waiver Requested

Minimal Risk*

Impact on Subject Rights and Welfare*

Waiver Essential to Research*

Additional Information to Subjects

Written Statement of Research*
No

If no written statement will be provided, please provide justificiation

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit

Potential Study Risks
There are minimal risks associated with the proposed study. The main risk is loss of confidentiality, which will be protected as described below. There are no potential risks associated with any other measures or data to be collected. During the consent process, we will inform subjects of the risks associated with loss of confidentiality.

Potential Study Benefits
We expect the proposed study to provide the first data on the impact of different types of sugary drink on adolescents purchases. We also expect this project to provide hands-on research training opportunities for Fogarty International Center trainees and fellows as well as educational opportunities for the broader INCAN research community.

Alternatives to Participation (optional)

Data and Safety Monitoring
As co-principal investigators, Drs. Roberto and Barnoya will meet by Skype conference calls weekly to assess the progress of the study. The biostatistician and research coordinators will also regularly join these calls. They will also have data and safety monitoring meetings every 6 months to more specifically assess the data quality, participant recruitment, accrual and retention, participant risk versus benefit, and study outcomes. The research team will also correspond by email and telephone as needed. Only the researchers involved in these studies and those responsible for research oversight will have access to the identifiable information provided. The data collected as part of this study poses minimal risk to its participants.

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit Assessment
Participants in this study will not receive any direct benefits. Knowledge gained from the proposed series of studies will provide some of the first real-world data on the potential effect of sugary drink warning labels on adolescents purchasing behavior. The proposed research will also examine novel labeling strategies to communicate the health harms of over consuming sugary drinks. This research can help inform nutrition policy efforts in Guatemala. The risks of loss of confidentiality are minimal in this study. Thus, the benefits of this research to society at large far surpass the risks.

General Attachments

The following documents are currently attached to this item:

Questionnaires (b.purchaseassessmentsurvey.pdf)

Questionnaires (d.beveverageintakequestionnaire.pdf)

Questionnaires (e.beverageintakesurvey-bevq.pdf)

Additional forms (f.labeldesignconditions.pdf)

Recruitment materials (c.oralconsentform.pdf)

Informed consent form (a.consentform.pdf)

Cover Letter (coverletterguatemalawarninglabels.doc)

Supplemental form(s) (inclusionofchildren.doc)

Additional forms (references.pdf)