Document Coversheet

Study Title:

A Novel Sugar-Sweetened Beverage Reduction Intervention for Native American Men (Indigenous SIPin)

Institution/Site:	Roswell Park Comprehensive Cancer Center
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ROSWELL PARK CANCER INSTITUTE

Title: A Novel Sugar-Sweetened Beverage Reduction Intervention for Native American Men (Indigenous SIPin)

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Roswell Park Study Number: I-810620

Consent Form Given to Participant Taking Part in a Research Study

KEY INFORMATION ABOUT THIS RESEARCH STUDY

This is a research study being done by doctors at Roswell Park Cancer Institute. Research studies include only those people who choose to take part.

We are asking you to take part in this study because you are a male volunteer associated with the Native American (NA) athletic community.

Study Purpose: The purpose of this study is to test the feasibility and analyze pilot data of Indigenous SIPin (formally named the adapted SIP*smart*ER Lacrosse program), with men associated with the NA athletic community.

Sugary drinks are the largest single source of calories in the US diet. Native Americans drink almost two times more sugary drinks than other racial groups in the US. This is a problem because sugary drinks are the biggest source of sugar in most people's diet. Natives also have very high rates of sugar-related health problems, like obesity and obesity-related cancers. This research was designed to try to help Native men drink fewer sugary drinks and hopefully have improved long term wellness.

Roswell Park Cancer Institute is offering a 6-month health program. The purpose of the program is to help reduce the number of sugary drinks you drink. The results of this study will be used to help us understand how Native American male athletes make changes in their sugary drink behaviors.

Study Duration and Number of Participants: It is expected that this study will take about 2 years to complete participant enrollment and analysis. We expect to enroll up to 40 participants from the Western NY area in the first and second year. We plan for an analysis period of 6 months after the last participant has completed their 6-month follow-up assessment.

Your participation in this study will be for approximately 6 months from first assessment until the completion of the following 6-month assessment.

For Native American and non-Native study volunteers, your participation in this study will be from the day you consent until the completion of the 6-month assessment.

Assessments: If you take part in this study, you will have two health screenings and an educational intervention program. Over a season, there are typically 12 lacrosse games that are played on a weekly basis. The study will recruit at both lacrosse games and other athletic events. Either before or after games/practices/competitions, we will give a half-hour class about how to improve wellness and drink fewer sugary drinks. We will also send helpful information and reminders using text messages to the men who attend the classes.

During the 6 months while on study, you will have in-person group meetings and delivered text messages. There will be 12 weekly in-person group lessons that are 30 minutes each and 27 text messages throughout the duration of the study. Lessons will likely take place after games, competitions or practices in the locker room. Texts will likely be sent twice a week for the first 12 weeks, and then monthly for the remainder of the 6-month intervention. In all participants, assessments will be collected at baseline and 6-months.

For study volunteers, you will have in-person group meetings and monthly text messages for the remainder of the 6-month intervention. Lessons will likely take place after games, competitions or practices in the locker room. Assessment will be collected after the time of your consent and at 6-months.

Costs: For most participants, there are no costs associated with this study.

However, if your cell phone carrier charges you for text messages, you will be responsible for any charges incurred from your cellular service provider as a result of any texts sent by the study. Standard rates/fees of your cellular service provider for receiving text messages will apply. The study will not reimburse you for carrier charges. If you have any questions, please be sure to consult your cell phone service provider in regards to your individual plan.

Risks: In the past, research has harmed many Native communities. To prevent that, we will work with our community partners and community advisory board. The research is a collaborative effort to prevent harms to the Native communities and people involved.

There are minimal risks for being involved in this study. While you take part in this study, you may be at risk for stress or anxiety from the health screening. You will always have the right to refuse to participate or to answer any questions in the health screening. If you become too tired during the health screening, you can take a break or finish on another day. This study may include risks that are unknown at this time.

There is a slight risk that your participation will be revealed through an accidental privacy breach. To avoid this, no names or other information that could be used to identify you will be in any article or presentation. All efforts will be taken to protect your identity.

You should discuss these risks with your doctor/study investigator.

Potential Benefits: You understand there is no guarantee that being on the study will help you. Future participants and NA community members may be helped from the results and information gained from this study.

Other Options: It is your decision to join. The other option is not to join. There are no penalties for not taking part in this study. You can leave the study at any time. If you decide to leave the study we ask that you notify Roswell Park Cancer Institute at 716-845-8845.

The type of study, the risks, benefits, discomforts, and other important information about this study are discussed below.

ADDITIONAL INFORMATION ABOUT THIS RESEARCH STUDY

It is important that you read and understand the following facts that apply to anyone that takes part in our studies:

a) This study is considered research. It is investigational.
b) Taking part in the study is voluntary.
c) You may withdraw from the study at any time without penalty, loss of any benefits or access to care at Roswell Park to which you are otherwise entitled.
d) Personal benefit may not result from taking part in the study, but knowledge may be gained that will benefit others.
e) If we become aware of important new information that may relate to your willingness to participate in this study we will inform you of this new information.

1. Will I be informed of research results?

If we learn new information from research tests or analyses during this study that may be important to your health or to your disease or condition, we will share that information with you. Such information will be provided to you at study assessment one and shortly after the 6-month follow up via a confidential personalized report.

2. Why would I be taken off the study early?

You may be taken off the study for any of the following reasons:

- You do not follow the study schedule or requirements
- New information becomes known to us that would change your decision to remain on the study

3. What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Attend study sessions
- Participate in the first (Baseline) Assessment, or if you are a study volunteer, after the time of your consent to the program
- Participate in the second (6-month Follow-up) Assessment

4. Will I be paid for joining this study?

You will receive the following payment for participating in this study:

You will receive a $25 dollar gift card for the first health screening and a $50 gift card upon completion of the second health screening.

5. Who do I contact if I have questions?

You are free to ask questions at any time about this study and to ask for more information from the doctors identified on this consent. If you have any questions, concerns, or complaints about this study, you should contact Rodney C. Haring, PhD at (716) 845-4920 at Roswell Park Cancer Institute.

If you have questions about your rights as a research participant or you feel you have been injured as a result of your participation in this research study, you can call study investigator at (716) 8454920 or the Office of Research Subject Protection at Roswell Park: (716) 845-3455. You should also feel free to contact the Center for Indigenous Cancer Research (CICR) (716) 845-8130 at any time while considering participation, during participation or once your participation is complete. This office is unaffiliated with any specific research study. They can help you obtain additional information regarding your research participation and your rights as a research participant or how to proceed should you feel you have been injured as a result of your participation. They are available to discuss any problems, concerns, questions or input you may have.

It may be necessary to contact you at a future date regarding new information about this research study. For this reason, we ask that you notify the study investigator at (716) 845-4920 or the Center for Indigenous Cancer Research (CICR) (716) 845-8130.

What about confidentiality?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information collected in this study may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your information, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect the study records and your information. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.

Certificate of Confidentiality

As an additional measure to protect your privacy, a Certificate of Confidentiality has been issued from the United States Government, National Institutes of Health, for this study. With this Certificate, the investigators and institutions involved in this study cannot be forced to disclose

information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. We will use this Certificate to resist any demands for information that would identify you, with the following exceptions:

- The Certificate cannot be used to resist a request for your information from the United States Government when the information is to be used for auditing or evaluation of federally funded projects
- State law requires we report cases of diseases that spread easily, or abusive behavior (toward a child, a partner, or an elderly person), and people who say they are going to hurt themselves or someone else.
- The Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or involvement in this research. Also, if you have given written consent to an insurer, employer, or other person to receive research information, then we may not use the Certificate to withhold the information.

Statement of Investigator/Person Conducting the Informed Consent Discussion:

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained and that any questions about this information have been answered. A signed copy of this consent will be given to the participant.

SIGNATURE_____ **DATE**_____ **TIME**_____

PRINTED NAME _____

Participant's Statement of Consent:

By signing below, you agree that:

- You have been told of the reasons for this study.
- You have had the study explained to you.
- You have had all of your questions answered, including those about areas you did not understand, to your satisfaction.
- You have carefully read this consent form and will receive a copy of this form.
- You do **not** waive any **legal** rights you have under federal, state, or Tribal laws and regulations.
- You willingly give your consent to voluntarily join in this research study.

Participant:

SIGNATURE_____ **DATE**_____ **TIME**_____

PRINTED NAME _____

Witness Signature is needed in the following circumstances – check below:

☐ Not Applicable
☐ The person consenting cannot write – mark must be made as appropriate.
☐ The person consenting cannot read - consent has been read to him/her.
☐ The person consenting cannot understand English and the consent has been verbally interpreted. (The witness should be fluent in both English and the language of the person consenting.)

Witness Statement:

The person consenting has signed this document in my presence.

SIGNATURE_____**DATE**_____ **TIME**_____

PRINTED NAME _____

RELATIONSHIP TO PARTICIPANT_____