

Document Coversheet

Study Title:

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

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PROTOCOL TITLE:

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

PROTOCOL NUMBER:

I 810620

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1 OBJECTIVES

The purpose of this study is to adapt an evidence-based Sugar Sweet Beverage (SSB) intervention (SIPsmartER) that reduces SSB intake so it is culturally appropriate for men affiliated with Native American athletics communities (SIPsmartER Lacrosse).

Specific Aim 1: Create an evidence-based culturally appropriate Sugar Sweetened Beverage (SSB) intervention for men affiliated with Native American athletics communities (SIPsmartER Lacrosse).

- Objective: Conduct and analyze qualitative data from focus groups and key informant interviews with Native American community members including Native American leaders and community members to develop SIPsmartER Lacrosse.

Specific Aim 2: Feasibility and pilot testing of adapted Indigenous SIPin intervention (previously named the adapted SIPsmartER Lacrosse program)

2 BACKGROUND

SSB intake in the US and disparities in Native Americans (NA)- Specific to soda/pop, US consumption has increased an estimated fivefold since 1950.⁵ When considering all SSB (e.g., soda/pop, sweet tea, sports and energy drinks, fruit drinks), SSB is the largest single source of calories in the US diet and contributes approximately 7% of total energy intake for US adults.⁶ Among NA, SSB intake is disproportionately higher and contributes an average of 12% of total energy intake – nearly twice as high as national estimates⁷. More specifically, indigenous data suggest the overall added sugar comprises an estimated 15% of total energy intake among adults (nearly twice as high as recommendations)^{8, 9}; and liquid sources of added sugar (i.e., SSB) contribute to 64% of this intake⁷. While both national and NA-specific data show SSB is the largest contributor to added sugar intake^{6, 7, 10}, excessive SSB consumption is undeniably pervasive in NA.

NA bear a disproportionate burden of all SSB-associated chronic health conditions¹⁸⁻²¹, including higher mortality from several^{22, 23} obesity-related cancers²⁴ (e.g. stomach, gallbladder, kidney). Although the data regarding NA men are scarce, the existing data report an even higher prevalence of hypertension (38.7%) in men compared to NA women (30.2%)²⁵. An SSB intervention for NA is clearly needed to address the alarming disparities among NA in both SSB intake and its associated chronic health conditions.

Evidence on the adverse consequences of excessive SSB consumption is compelling.²⁶⁻³⁶ Accumulated evidence demonstrates strong relationships linking SSB consumption with numerous chronic health conditions. Findings from several recent systematic reviews, meta-analyses, and prospective cohort studies demonstrate substantial and consistent evidence across multiple studies on the negative health consequences of excessive SSB intake, including obesity,^{26, 27} diabetes,^{28, 29} some types of obesity-related cancers,^{30, 31} coronary heart disease,³² hypertension,^{33, 34} and dental decay.^{35, 36}

Limitations of current efforts

SSB intake has been a primary or other outcome within the context of obesity control interventions in numerous studies³⁷. These studies have targeted predominately European or white children and youth through school-based³⁸⁻⁴³ or family-based interventions⁴⁴⁻⁴⁶ and a recent meta-analysis

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concluded that SSB interventions were generally effective in reducing SSB intake among children³⁷.

A growing literature has begun to document effective SSB interventions for adults. Current interventions have targeted: 1) overall diet quality; 2) chronic disease reduction, including obesity control; or 3) SSB intake specifically. Although dietary interventions have not been successful in reducing SSB intake among specific groups (young adults^{47, 48}, Australian mothers⁴⁹, predominately white female adults⁵⁰), comprehensive chronic disease prevention interventions have generally reported modest decreases in SSB intake (e.g. 0.11 (.05) SSB serving per day reduction⁵¹; 3.5 oz difference between treatment and control⁴⁹) among diverse samples⁵². Interventions targeting SSB intake as the primary outcome have reported even greater reductions in SSB intake than chronic disease prevention interventions. In their 9-month SSB intervention for overweight Mexican women (n=189), Rodriguez-Ramirez et al.⁵³ reported significant between group differences from baseline to 9-months follow-up, whereby their treatment group reduced SSB intake by 710ml/day compared to a 322ml/day reduction in the usual care group. Similarly, Tate et al.⁵⁴ reported that their treatment groups (replacing SSB with diet beverages, replacing SSB with water) reduced their kcal from beverages from baseline to 6-months by 259.8kcal and 187.4kcal, respectively, compared to the control group, which reduced their kcal from beverages by 106.7kcal. Tate et al.'s 6-month behavioral intervention study included 318 overweight or obese adults, the majority of whom were white or black women. Further, our team developed SIPsmartER, a behavioral intervention that reduced SSB intake by 227kcal (-326,-127) in a predominately white, female, underserved sample from baseline to 6 months⁵⁵.

Thus, to date, successful SSB interventions have been developed for children, and there is evidence for effective SSB reduction interventions in adults when SSB is the primary outcome. However, current interventions have reached only or predominately (80%⁵⁴-81%⁵⁵) women⁵³. Further, the engagement of diverse samples has been limited, with no focused SSB interventions including NA. There are currently no effective SSB interventions for both men and NA adults; considerable gaps the proposed study would fill.

Although SSB interventions have not been implemented in NA communities, prior behavioral interventions offer some insights in developing an effective SSB intervention for NA men. The Special Diabetes Program for Indians Diabetes Prevention, which includes a substantial dietary change component, has reported a modest sustained weight loss in 8,652 NA participants, with subsequent decrease in diabetes risk. This supports the promise of adapting evidence-based interventions (i.e. Diabetes Prevention Program)⁶⁴ for NA populations. However, the program enrolled predominately women (>70%) and reported high attrition rates (64-87%) after just one year⁶⁴. This is consistent with information from our Community Advisory Board (CAB), who communicated that prior health programs where NA men were asked to come to a specified place to receive an intervention (like the Special Diabetes Program for Indians Diabetes Prevention) resulted in low attendance. Our CAB stressed that NA men in their community would not come to a health program unless it is held in a place and setting where they are already engaged, like lacrosse games.

Lacrosse as a promising way to engage NA men in health

Among NA, lacrosse has been practiced for centuries⁶⁵. The sport celebrates the strengths of NA communities and reflects the community's emphasis on the interconnections we have between our body, spirit, and Mother Earth (nature, the land). Lacrosse is not only considered a sport but also

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a medicine game to bring healing to communities. Historically, disputes between neighboring tribes were settled by lacrosse instead of war. Among the Haudenosaunee (a Confederacy consisting of six Nations; the Seneca Nation of Indians is one of these Nations), lacrosse is a medicine game that is played for the enjoyment of the Creator. Lacrosse has and continues to be a major community event in NA communities⁶⁵.

Prior research conducted with NA and other indigenous communities have identified the promising intervention strategy of group-based interventions^{66, 67}. Social cohesion and NA identity are considerable strengths within NA communities that can be built upon through engaging groups—such as lacrosse teams—in intervention research. NA scholars have also identified friendly competition as a way to engage and sustain community participation in interventions⁶⁶. This friendly competition is evident in the sport of lacrosse, which is widely attended by NA communities⁶⁶.

3 STUDY ENDPOINTS

- Conduct formative work with Native American community members using qualitative methodology, including focus groups and in-depth interviews to understand opportunities and barriers within the Native American culture and SSB intake.
- Conduct content analysis of qualitative data collected.
- Adapt evidence-base intervention materials (SIPsmartER) to create an SSB intervention for men affiliated with Native American athletics communities (Indigenous SIPin).
- Test the feasibility and analyze pilot data of Indigenous SIPin with men affiliated with NA athletics communities.

4 LOCAL AND STUDY-WIDE NUMBER OF SUBJECTS

Aim 1: It is anticipated that up to a total of 60 qualitative interviews will be conducted in the form of structured interviews and focus groups.

Aim 2: Test feasibility and pilot intervention with up to 40 participants.

Therefore, a total of 100 participants will be with the study.

5 STUDY TIMELINES

Study Timeline

ACTIVITY BY QUARTER	Year 1				Year 2			
	1	2	3	4	1	2	3	4
Obtain ethical approvals	X							
Recruit for formative work	X	X	X	X	X	X	X	X
Conduct formative work		X	X					
Analyze data			X	X				
Culturally adapt Indigenous SIPin			X	X				
Test feasibility and pilot culturally-					X	X	X	X

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adapted Indigenous SIPin

ACTIVITY BY QUARTER		Year 1				Year 2			
		1	2	3	4	1	2	3	4
Aim 1	Obtain ethical approvals	X							
	Recruit for formative work	X	X	X	X	X	X	X	X
	Conduct formative work			X	X				
	Analyze data			X	X				
	Culturally adapt Indigenous SIPin			X	X				
	Test feasibility and pilot culturally-adapted Indigenous SIPin					X	X	X	X
Aim 2	Obtain ethical approvals					X	X	X	X
	Recruit for formative work					X	X	X	X
	Conduct formative work							X	X
	Analyze data							X	X
	Culturally adapt Indigenous SIPin								
	Test feasibility and pilot culturally-adapted Indigenous SIPin								

6 SETTING

We have existing community partners across the six Nations in the Iroquois or Haudenosaunee Confederacy, whose original ancestral lands spanned across what is known today as New York State, Ontario, and Quebec, Canada. We will work with our urban and sub-urban (off reservation or off-territory) community partners to identify appropriate recruitment strategies for participation in the qualitative interviews and focus groups. Community partners will include off-territory leaders, health care providers, elders, community center directors and members. We have also identified Native American lacrosse organizations with Native American males, living off-territory (Buffalo and Rochester) in either urban or sub-urban settings that we will recruit from. Lastly the Center for Indigenous Cancer Research (CICR) Community Advisory Board (CAB) will be involved in the process of developing stakeholder interview and focus groups questions. The CICR CAB is made up of members from the Haudenosaunee Confederacy.

This study will use virtual platforms, when necessary due to COVID-19, to perform project related duties including recruitment, consent, and implementation of community-based outreach. Otherwise in-person interviews and focus groups will be conducted at Native American Community Services and the Rochester Native American Cultural Center, our urban/sub-urban partners.

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For Aim 2, the not-for-profit, Tuscarora Athletics, a Native American owned 501-C is a collaborating partner (LOS; **Appendix H**). The board and organization are from the Tuscarora Indian Nation and region. However, the games and organization are based off-territory, off-reservation, and the research will be conducted in-person in an urban setting and/or virtually.

7 INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria

To be included in this study, subjects must meet the following criteria:

Stakeholder interviews/Focus Group

1. At least 18 years or older
2. Research conducted on tribal lands require tribal government approval. Our project will not be occurring on tribal lands. The project will be working with Native organizations off-territory.
3. Participants only must own a smart device in order to receive study text messages.
4. Aim 2 participants must understand the investigational nature of this study and sign an Independent Ethics Committee/Institutional Review Board approved written informed consent form prior to receiving any study related procedure.

Exclusion Criteria

Subjects will be excluded from this study for the following:

1. Research conducted on tribal lands require tribal government approval. Since we do not currently have tribal government approval, our project will not be occurring on tribal lands.

Inclusion of Women and Minorities

Both men and women and all races and ethnicities are eligible for Aim 1 of this study. The focus of the project is NA men. However, only men (of all races and ethnicities) will be recruited for Aim 2.

Special Populations

The following special populations may be included in this study:

- Pregnant women; the study Aim 1 does not impose risk to the pregnant woman and/or fetus

The following special populations will be excluded from the study:

- Cognitively impaired adults/adults with impaired decision-making capacity
- Individuals who are not yet adults (infants, children, teenagers)
- Prisoners.

8 LOCAL AND STUDY-WIDE RECRUITMENT METHODS

Roswell Park's marketing team, creative services, and the CAB will develop culturally sensitive flyers, brochures, and recruitment and retention materials. Recruitment materials will be distributed to Native urban partners and athletic organizations in Buffalo, NY and Rochester, NY along with other places NA members regularly gather. Study staff will also assist with recruitment

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and retention across Native urban partnerships. Together with Dr. Haring, the team will recruit at tribal workplaces with supervisors, directors, and managers that work with men, families, and cultural programming. To assist with study retention, we will ask participants for their contact information. We will also use a study recruitment flyer (**Appendix A: Aim 1; Appendix G: Aim 2**) to be used for all email correspondence and ad messaging that we send/post. Additionally, for Aim 2, incentives of \$25 (gift card) will be provided at baseline and \$50 (gift card) at 6-month assessment. Additionally in Aim 2, the potential program incentive(s) (e.g., water bottle, fruit infuser, etc.) will be given to participants. Native American and non-Native study volunteers who opt to consent and become participants will receive the same incentives as prior participants: \$25 (gift card) will be provided at the time of their consent and first assessment and \$50 (gift card) at 6-month assessment. The mode of delivery (e.g., in-person or shipped) and time of the delivery for program incentive(s) will be based on the participant's preference. Lastly, social media will be used as a means to recruit and retain participants over time. The project will work closely with the CICR Community Advisory Board and partnering not-for-profit along with RP marketing and communications.

9 CONSENT PROCESS

For Aim 1 participants, we will perform a verbal consent process at the beginning of the focus group/interview discussion in the room in which the participants and facilitator gather for the discussion (See **Appendix B & Appendix C**). Participants will have an opportunity to ask questions throughout the verbal consent process and at the end. Participants will be informed that they can also ask questions at any time during the focus group discussion. The focus group facilitator (Dr. Haring; Maybee; Henry; or Abrams) will ask participants if they understand the information presented to them in the verbal consent script. To minimize the possibility of coercion or undue influence, participants will be informed that they can stop participating at any time during the discussion without any penalty or loss of benefits to which they are otherwise entitled.

For Aim 1 participants, we request to waive the requirement to obtain written documentation of consent. There will be no signed consent. Verbal consent will be obtained from participants prior to the any assessment (See attached Informational Sheet for Study Participation).

For Aim 2 participants, a written consent will be completed and signed before Aim 2 study procedures commence. Study participants that have signed their consent prior to 8/29/22 will be contacted by study staff by phone call or text message at their next lesson, informing them of the potential program incentive(s).

To comply with the ethical guidelines set forth by the Institutional Review Board (IRB), an additional consent form is required due to the increased participation of multiple volunteer players in the lacrosse sessions and the Sugar Sweetened Beverage Intervention. Therefore, starting on 6/13/2023, it is necessary to notify all study volunteers, Native and non-Native, during their next lesson about the need to provide consent for the completion of the follow-up assessment. This consent will ensure that participants fully understand the study's objectives, procedures, and potential risks, and that their rights and privacy are protected. Obtaining this additional consent is crucial to maintaining the integrity and ethical conduct of the study, and to facilitate accurate evaluation of the intervention's impact on Native American male lacrosse players who voluntarily joined the intervention beyond the initial baseline assessment. After baseline assessment, we received a high number of study volunteers. Volunteers were defined as individuals who voluntarily chose to opt into the program after the formal intervention design was established.

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Their participation and consent to be part of the study are essential for evaluating the effectiveness and outcomes of the intervention. By opting in, these individuals have expressed their willingness to engage in the program and contribute to the research objectives.

This study will not be initiated until the protocol and informed consent document(s) have been reviewed and approved by a properly constituted Institutional Review Board (IRB) or Independent Ethics Committee (IEC). Each participant shall read, understand, and sign an instrument of informed consent prior to performance of any study-specific procedure. It is the responsibility of the investigator to ensure that the participant is made aware of the investigational nature of the treatment and that informed consent is given.

The Investigator is responsible for the retention of the participant log and participant records; although personal information may be reviewed by authorized persons, that information will be treated as strictly confidential and will not be made publicly available. The investigator is also responsible for obtaining participant authorization to access medical records and other applicable study specific information according to Health Insurance Portability and Accountability Act regulations (where applicable).

This study will be conducted in compliance with all applicable laws and regulations of the state and/or country and institution where the participant is treated. This study will be conducted in accordance with the ethical principles embodied in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, consistent with good clinical practice and the applicable regulatory requirements and according to the guidelines in this protocol, including attached appendices.

For Single-Site Study: The Roswell Park SOP: Informed Consent Process for Research (HRP-090) will be followed.

10 PROCESS TO DOCUMENT CONSENT IN WRITING

The Roswell Park “SOP: Written Documentation of Consent (HRP-091)” will be followed.

For Aim 1 participants, we request to waive the requirement to obtain written documentation of consent. Verbal consent will be obtained from participants prior to the any assessment (See attached Informational Sheet for Study Participation).

For Aim 2 participants, a written consent will be completed and signed before Aim 2 study procedures commence. For study volunteers a written consent will be completed and signed before Aim 2 follow-up assessments and procedures commence.

11 PROCEDURES INVOLVED

Specific Aim 1: Collaborate with key stake holders and lacrosse teams to culturally adapt SIPsmartER Lacrosse (Indigenous SIPin)

We will collaborate with our CAB in the indigenous methodologies data collection and analysis process to do the following: 1) Qualitative data collection, which will include individual interviews and focus groups (creating interview and focus group questions); 2) Content analysis of qualitative data.

Indigenous methodologies use an indigenous-centered research process that incorporates qualities of community-based participatory research with a specific focus on the needs of indigenous

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communities.² The value of indigenous methodologies is the emphasis on indigenous knowledge as emerging from and being engaged with the mind, body, spirit, history, dreams, collective knowledge, and knowledge of the natural world and its rhythms.^{3, 4} This approach centers indigenous wisdom, and through ongoing CAB collaboration, returns the voices and knowledge of the community to the forefront of the indigenous research process.

Formative work to achieve Aim 1 will include individual interviews and focus groups. See **Appendix D** for focus group and interview guide and script. A series of focus groups and interviews will be conducted to ascertain culturally salient messaging to include in SIPsmartER Lacrosse. Formative work will include stakeholders and community members (i.e., off-territory, leaders, health care providers, elders, Native urban center staff and affiliates, NA males associated with the NA athletics community). Each interview will be about 60 minutes, whereas each focus group will be for about 90 minutes. *Eligibility criteria:* 1) at least 18 years or older; 2) resides in participating off-territory regions of Buffalo and Rochester, NY. *Recruitment:* We will use purposive sampling of stakeholders, and we will engage community health educators, community centers, and grass-roots groups to aid in coordinating the invitations of these identified NA community members to participate. Those meeting the eligibility requirements will be sent a letter informing them about the project and prospective interview or focus group dates. These interviews and focus groups will be conducted in virtual contexts and/or private, community-based settings. We will also collect basic demographics, tribal affiliations, tribal languages familiar with or spoken (See **Appendix E**). Participants will be given a \$25 gift card for their participation. NA study staff members trained in qualitative methodology will conduct the audio-recorded interviews or facilitate focus groups. Interviews and focus groups will be transcribed and de-identified for analysis.

Specific Aim 2: Test the feasibility of culturally adapted SIPsmartER Lacrosse (Indigenous SIPin)

The feasibility of SIPsmartER Lacrosse was assessed in Aim 1. The structure of the intervention and design was adapted from findings of Aim 1. This modification reflects the adapted version for Aim 2.

Training. Replicating her previously successful training model for SIPsmartER^{99, 100}, MPI Dr. Jamie Zoellner (external study Principal Investigator) will lead the training of project staff to implement **Indigenous SIPin**. Dr. Jamie Zoellner is a Professor at the University of Virginia and will assist in the adaptation of the proposed intervention and lead the training of the project staff once we initiate Phase 2 of the study. A training-of-trainers model that incorporates didactic education, trainee practice, and written and verbal feedback will be used to train staff¹⁰¹. The training will build knowledge about SSB behavior change, with a specific emphasis on delivering the intervention with fidelity, utilizing intervention materials to program the text messages, and communicating effectively with participants about health. The training will conclude with project staff demonstrating mastery of concepts through mock small group sessions and accurate text message programming. Project staff will be asked to complete a checklist of topics to monitor intervention fidelity.

Aim 2. The adapted SIPsmartER Lacrosse program was renamed **Indigenous SIPin**. The redesigned and culturally adapted program is found in **Appendix I** “SipIN Lesson Plan Crosswalk”. In summary, participants in the Indigenous SIPin intervention during the 6-month study will have in-person and/or virtual group meetings and delivered text messages. There are

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12 weekly in-person and/or virtual group lessons which are 30 minutes each and 27 text messages throughout the duration of the intervention. Lessons will likely take place after athletic contests 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. Volunteer participants who joined the study will be provided with the opportunity to opt-in and join the program, thus becoming eligible to receive follow up monthly text messages throughout the remainder of the six-month intervention. These participants will also undergo the 6-month assessment process, which includes data collection at the time of their consent and during the six-month follow-up period. This comprehensive assessment will enable us to evaluate the intervention's effectiveness and monitor the participants' progress over the course of the study. By extending the option to join the program and receive text messages, we aim to include all eligible volunteers and ensure that their participation contributes to the overall objectives of the study.

12 WITHDRAWAL OF SUBJECTS

Participants can stop their participation at any time. Participants may refuse to answer any question and they may leave at any time.

13 RISKS TO SUBJECTS

In both Aims 1 and 2, risks include the potential loss of confidentiality since the focus groups or team activities may be conducted in a community setting with small groups of participants –. We will inform interested individuals when they call that they will participate in a group discussion or team activity with up to 9 other community members (focus groups) or 19 per group for team activities (multiple teams) who they may or may not know. We will inform participants that we do not want them to state their name at any time during the focus groups or team activity or share information from the focus groups, team activities including the identification of other participants, outside of the focus groups/team activities, although we cannot fully guarantee that other participants will adhere to this request. Discussion of SSB and its associated health risks may be uncomfortable for some participants. We will assure participants that they do not have to discuss or answer any of the focus group/team activity questions that they are not comfortable with, and that they can stop participating at any time without penalty to any services for which they are otherwise entitled to.

14 POTENTIAL BENEFITS TO SUBJECTS

There is no direct benefit. The Aim 1 focus group discussions and stakeholder interviews will identify culturally salient messages to reduce SSB intake for the purpose of developing an SSB reduction intervention for NA men. If the intervention is proven successful, the health of participants would improve and results may be generalizable to other Indigenous communities. There are no anticipated benefits from Aim 2, the intervention, although participants may experience some improvements in their health due to decreased intake of sugar sweetened beverages.

15 SHARING OF RESULTS WITH SUBJECTS

In Aim 1, we will not share information of the focus groups and interviews with subjects. Rather, we will use the qualitative data to inform the cultural tailoring of the educational materials and

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activities that will be included in SIPsmartER Lacrosse. In Aim 2, de-identified aggregate results will be shared back to the partnering organization. Individual results will be shared with each participant at study assessment one and shortly after the 6-month follow up via a confidential personalized report.

16 ECONOMIC BURDEN TO SUBJECTS

Study-related texts may result in charges to participants based on individual participant's cell phone carrier plans. Participants will be responsible for any carrier fees.

17 PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS

Only de-identified data will be accessed and recorded. Data files will be coded numerically and assigned to each participant. Electronic copies of data collection records will not include protected health information. Information gathered from participants will remain anonymous and will be referred to only by general category. There will be no reference by name to any participant in any qualitative or quantitative data capture. No participant identity will be disclosed in the event of publication or sharing of data.

The data collected from this study will be organized by a unique identification number assigned to the participant so that their identity will be available only to project staff and will remain completely confidential. The data manager, study staff, Co-Is and PI of the study will have access to the data records.

All study records will be kept electronically in Roswell Park maintained and secured equipment. The electronic data records will be saved and secured on the Roswell Park shared server. Survey data will be electronic. All participant-related forms will be kept in a locked room where it will remain for approximately five years following the completion of the project.

18 VULNERABLE POPULATIONS

N/A

19 DATA AND SPECIMEN BANKING

N/A

20 SAFETY REPORTING

In Aim 1, involvement in this study does not involve any physical risk. In Aim 2, although participants may be part of a physical activity, the study focuses on engaging before or after the physical activity, and the physical activity is not part of the research intervention.

Unanticipated Problems

An Unanticipated Problem (UP) is any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given:
 - The research procedures that are described in the study-related documents, including study deviations, as well as issues related to compromise of participant privacy or confidentiality of data.

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- The characteristics of the participant population being studied.
- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized and if in relation to an AE is also deemed Serious per Section 17.7.

Reporting Unanticipated Problems

Unanticipated problem reporting will begin at the time of participant consent. The Reportable New Information (RNI) Form will be submitted to the CRS Quality Assurance (QA) Office within 1 business day of becoming aware of the Unanticipated Problem. After review, the CRS QA office will submit the RNI to the IRB.

When becoming aware of new information about an Unanticipated Problem, submit the updated information to the CRS QA office with an updated Reportable New Information Form. The site Investigator or designated research personnel will report all unanticipated problems to the IRB in accordance with their local institutional guidelines.

21 DATA MANAGEMENT AND CONFIDENTIALITY

Oral consent will be received from participants prior to their completion of the community round table (Aim 1). Written consents will be used for Aim 2 (Appendix J). All participants may refuse to answer any of the assessment questions. Only de-identified data will be accessed and recorded. Data files will be coded numerically and assigned to each participant. Electronic copies of data collection records will not include protected health information. Information gathered from participants will remain anonymous and will be referred to only by general category. There will be no reference by name to any participant in any qualitative or quantitative data capture. No participant identity will be disclosed in the event of publication or sharing of data.

The data collected from this study will be organized by a unique identification number assigned to the participant so that their identity will be available only to project staff and will remain completely confidential. The data manager, study staff, Co-Is and PI of the study will have access to the data records.

Only de-identified data will be sent and reviewed by the external study staff members. Only internal Roswell study staff will have access to identifiable data.

All study records will be kept electronically in Roswell Park maintained and secured equipment. The electronic data records will be saved and secured on the Roswell Park shared server (path name: HealthDisparity on 'CancerPrev\Cancerprev\$\Epidemiology'(S:)) Qualitative data will be filed in a locked cabinet located in the Roswell Park Center for Indigenous Research Offices, Carlton House and will not be taken off Roswell Park premises. The data will be kept in a locked room where it will remain for approximately five years following the completion of the project.

22 STATISTICAL PLAN

For Aim 1, Dr. Haring and Co-I Dr. Emily Haozous (external Co-Investigator) are both qualitative experts who have prior expertise in qualitative methodology with NA communities^{2, 92-96} and will conduct the analysis. Dr. Haozous is an assistant professor at the University of New Mexico

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College and will also assist in the adaptation and development of the intervention and assist with qualitative analysis of the formative interviews. Any discrepancies will be brought to the team and the CAB for resolution. We will use ATLAS.ti to facilitate our analysis. We will use directed content analysis^{97, 98} through an iterative process of coding, clustering, and categorizing de-identified transcripts. We will conduct these analyses independently but will meet regularly to compare coding practices to confirm consistency throughout the coding process. Once all interviews are coded, we will meet to discuss the clustering and categorization process to identify preliminary sub-themes and themes. Through this process, results of the analysis will inform the development of SIPsmartER Lacrosse.

To ensure a participatory process, the research team will meet with the CAB to introduce the research process and receive specific feedback on the interview and focus group guides. This meeting will focus on ensuring the guides are designed to generate the best possible data without inflicting cultural harm. The CAB will also review SIPsmartER's intervention materials and provide feedback regarding how to make it more relevant for NA men.

Intervention adaptation: With extensive expertise in adapting evidence-based behavioral interventions for rural, diverse groups¹⁰²⁻¹⁰⁶, Drs. Yeary and Zoellner will lead the adaptation process. SIPsmartER⁷⁰ consists of 3 in-person group classes (60-90 minutes each), one live phone call (~15 minutes), and 11 IVR phone messages. We anticipate that the *core components* of SIPsmartER (culturally adapted to Indigenous SIPin) will largely remain intact, including the key learning objectives, evidence-based behavioral change techniques (e.g. personalized action planning, goals and planning, feedback and monitoring, social support), and health literacy techniques (e.g. clear communication, teach-back methods, message repetition).¹¹³ However, we highly anticipate findings from Aim 1 and our CAB meetings informed the *mode of delivery adaptations*, *target audience adaptations*, and *cultural adaptations*.

Aim 2: Piloting feasibility and cultural adaptation of Indigenous SIPin: Study design: MPI Yeary, MPI Haring and Co-I Haozous will lead the implementation of baseline and 6-month pre/post-test design, whereby participants (total n=40) will receive the Indigenous SIPin intervention. IRB approved study staff will deliver the intervention. Given discussions within our team, **Indigenous SIPin** will consist of 12 sessions (30 minutes per session) and 27 texts over 6 months (**Appendix I**, SIPin Lesson Plan Crosswalk). Study volunteers who have provided consent will receive monthly text messages exclusively for the remaining duration of the six-month intervention. We will compare primary (SSB intake), secondary (dietary intake, body weight) and other outcomes (historical trauma, cultural connection, resilience) pre-post. Outcomes will be assessed at baseline and 6 months. Study volunteers who opt-in to the study after the initial baseline assessment and provided consent will have their outcomes assessed at two key time points: at the time of their consent and again at the six-month follow-up. This is a feasibility study and pilot study which balances rigor with what is naturally occurring in the community. We did not randomize at the individual level because we did want to alter the community's normal process of forming lacrosse teams. Typically, no-treatment controls are unacceptable in community-based interventions.

23 COMMUNITY-BASED PARTICIPATORY RESEARCH

The stakeholder interviews and focus groups will be conducted with urban, rural, and sub-urban community members with coordination and support of Native urban centers. We will ask for their input to develop a culturally tailored sugar sweetened beverage intervention for men. The proposed

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study builds upon a lifetime partnership between lacrosse organizations and Dr. Haring. Dr. Haring is an enrolled member of the Seneca Nation of Indians and a resident of the largest reservation within the Seneca Nation of Indians. As a researcher, Dr. Haring has conducted numerous health promotion projects with the tribes over the past decade, including an NIH-funded diabetes prevention program adapted for NA men (R01DK102728), and three current NCI rural cancer center administrative supplements (PI or Co-PI) (P30CA016056) all focused on relationship building; understanding cancer care continuums with Indian Health centers; and clinical trial recruitment, retention, and education. Prior, Dr. Haring held a social work practice that contracted with tribes for over 15 years. Dr. Haring is also Director of the Roswell Park Center for Indigenous Cancer Research, the first of its kind in the Eastern US to continue Roswell Park's work with NA and other indigenous populations. Roswell Park is situated in the homelands of the Haudenosaunee or the Iroquois Confederacy—a league of Indigenous Nations who have the first treaties with the US. A basis of the center focuses on Haudenosaunee principals of strength, peace, and the “Good Mind”. Led by a Community Health Board of tribal members and leaders from across the tribes in NY, The Indigenous Center for Cancer Research combines efforts to address cancer and co-occurring conditions in Indian Country by working with Indigenous Nations on collaborative research. In 2016, Roswell Park established a federal MoU with Indian Health Services that outlined a framework to address cancer health disparities in Indian Country by focusing on direct service, capacity building, consultation, technical assistance, education, and research.

24 MULTI-SITE RESEARCH

N/A

25 PRIOR APPROVALS

For Aim 1, this research is not being conducted on the reservation/territory and will not need to go through tribal council approval. Thus, its focus will be on rural, urban, and sub-urban areas that are off reservation/territory. For Aim 2, the project is also not occurring on reservation/territory. However, the project is being supported by an Indigenous not for profit organization working off-territory in an urban setting. See Letter of Support (**Appendix H**).

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27 APPENDICES/ SUPPLEMENTS

Appendix A. Study Recruitment Flyer (Aim 1)

Appendix B. Study Information Sheet for Participation in Structured Interviews

Appendix C. Study Information Sheet for Participation in Focus Groups

Appendix D. Qualitative Interview Guide for Interviews and Focus Group

Appendix E. Study Demographics Questionnaire (Aim 1)

Appendix F. Study Data Collection Instruments (Aim 2)

Appendix G. Study Recruitment Flyer (Aim 2)

Appendix H. Letter of Support

Appendix I. SIPin Lesson Plan Crosswalk

Appendix J. Food Amount Booklet

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Appendix A. Study Recruitment Flyer (Aim 1)



The flyer has a purple background with white topographic line art in the corners. A central photograph shows lacrosse players in white and yellow uniforms huddled on a field. The text is in white, with the main headline in a large, bold font. The eligibility criteria are listed in a bulleted format. The incentive is prominently displayed in a large, outlined font. The logos for Roswell Park and the Center for Indigenous Cancer Research are at the bottom.

We need your voice!

The Center for Indigenous Cancer Research is looking for focus group and interview participants who would like share their views on adapting a healthy beverage program for lacrosse players.

Eligibility:

- 18 years or older
- Native or non-Native
- Resides off-territory in the Buffalo/Rochester region

\$25 GIFT CARD

FOR ELIGIBLE PARTICIPANTS

 **ROSWELL PARK**
COMPREHENSIVE CANCER CENTER

CENTER FOR INDIGENOUS CANCER RESEARCH

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Appendix B. Study Information Sheet for Participation in Structured Interviews

I am (*fill in name and role*), from Roswell Park Center for Indigenous Cancer Research. I am working with a project team at Roswell to develop a program for Native American men to reduce their sugary drink intake. Sugary drinks are drinks like pop, soda, and juice. The interview is aimed to help create a culturally appropriate sugary drink intervention for Native American men. This study is funded by a grant from the National Institutes of Health.

I would like to tell you more about it before you decide whether or not to participate. Please stop me at any time if you have any questions. Your participation is completely voluntary; you do not have to participate.

If you agree to take part in this interview you will be asked to respond to some questions about sugary drink intake, particularly what kinds of messages would help Native American men drink fewer sugary drinks. You will also be asked to volunteer some information about yourself including demographic information and contact information so that we may send text reminders. Your participation in this study today will take up to 60 minutes.

Your involvement in this study does not involve any physical risk to you. The possible risks might be feeling uncomfortable answering questions or embarrassment. You will not receive any direct health benefit from participating in this study.

You will receive a \$25 gift card for participating in this study.

You do not have to take part in this project. If you decide to participate, you can stop your participation at any time. You may refuse to answer any questions and you may leave at any time.

Results of this project may be used for developing a local outreach education program, for teaching, for research, for scientific publications and for presentations at scientific and community meetings. You will not be identified in any way.

This project may use virtual platforms, when applicable, to perform project related duties including recruitment, consent, and implementation of community-based outreach.

If you have any questions, you are free to ask them now. If you have questions later, you may contact me at the telephone number listed below.

If you have questions or concerns about the study at any time, you can call the Roswell Park Office of Research Subject Protection at (716) 845-3455. If you have any questions, you are free to ask them now. If you have questions later, you may contact me at the telephone number listed below. This study has been reviewed and approved by the Roswell Park Institutional Review Board to assure that the study plans will not put participants at risk.

CONTACT INFORMATION:

If you have any questions about this study, you may contact the study director:

Rodney Haring, PhD
Roswell Park Comprehensive Cancer Center
Elm & Carlton Streets
Buffalo, NY 14263
716-845-4920

Roswell Park Protocol Number: I 810620

Appendix C. Study Information Sheet for Participation in Focus Groups

I am (*fill in name and role*), from Roswell Park Center for Indigenous Cancer Research. I am working with a project team at Roswell to develop a program for Native American men to reduce their sugary drink intake. Sugary drinks are drinks like pop, soda, and juice. The interview is aimed to help create a culturally appropriate sugary drink intervention for Native American men. This study is funded by a grant from the National Institutes of Health.

I would like to tell you more about it before you decide whether or not to participate. Please stop me at any time if you have any questions. Your participation is completely voluntary; you do not have to participate.

If you agree to take part in this focus group you will be asked to sugary drink intake, particularly what kinds of messages would help Native American men drink fewer sugary drinks. You will also be asked to volunteer some information about yourself including demographic information and contact information so that we may send text reminders. Your participation in this study today will take up to 90 minutes.

Your involvement in this study does not involve any physical risk to you. The possible risks might be feeling uncomfortable answering questions, embarrassment, or someone identifying you as a participant in the group, although this would be rare. You will not receive any direct health benefit from participating in this study.

You will receive a \$25 gift card for participating in this study.

You do not have to take part in this project. If you decide to participate, you can stop your participation at any time. You may refuse to answer any questions and you may leave at any time.

Results of this project may be used for developing a local outreach education program, for teaching, for research, for scientific publications and for presentations at scientific and community meetings. You will not be identified in any way.

This project may use virtual platforms, when applicable, to perform project related duties including recruitment, consent, and implementation of community-based outreach.

If you have any questions, you are free to ask them now. If you have questions later, you may contact me at the telephone number listed below.

If you have questions or concerns about the study at any time, you can call the Roswell Park Office of Research Subject Protection at (716) 845-3455. If you have any questions, you are free to ask them now. If you have questions later, you may contact me at the telephone number listed below. This study has been reviewed and approved by the Roswell Park Institutional Review Board to assure that the study plans will not put participants at risk.

CONTACT INFORMATION:

If you have any questions about this study, you may contact the study director:

Rodney Haring, PhD
Roswell Park Comprehensive Cancer Center
Elm & Carlton Streets
Buffalo, NY 14263
716-845-4920

Roswell Park Protocol Number: I 810620

Appendix D. Qualitative Interview Guide for Interviews and Focus Group



Focus Group/Individual Interview Script

Introduction

"Hello everyone, my name is _____ [provide a brief introduction of yourself]. I am helping with a study being conducted by the Roswell Park Center for Indigenous Cancer Research. This study that will help us understand what kind of health messages males associated with the Native American community would prefer to receive for a future program that we are designing to reduce consumption of sugar-sweetened beverages. You are currently attending the first part of this study- the focus group and/or individual interview and it may be in-person or virtually. I would really appreciate your help today in informing me about your opinions and preferences for health messages. We are interested in developing a sugary sweetened beverage reduction program for males within the Native American communities in the Buffalo NY and Rochester NY regions, so the information you provide will help us better understand the needs of your lacrosse community so we can make the future program better. Any feedback is welcome and any information you can give will be very helpful to me and my project."

Informed Consent (oral)

"Before we begin, we will go over the informed consent. After reading through this together, you will have time to ask any questions and obtain any clarifications. If you agree to what shared. We will then begin the focus group or individual interview." *[Read informed consent document & address any questions.]*

Sugar-Sweetened Beverage Intake, Demographics Questionnaire

"Before we introduce you the health messaging portion of this focus group or individual interview, we want to collect some brief demographic information. We will either email or send a virtual version for you to fill out and return."

SIPSmartER Introductory

"We want to begin by giving you a brief overview of the SSB reduction program that we are developing. This will help you understand why these health messages are being developed and how your feedback is so important." *[Go through presentation & address questions]*

Break – 5 minutes

Health Message Ranking and Sorting Activity

"We are now passing around sets of notecards (or displaying virtually). Each set corresponds to one topic area that we would like to address with health messages. As you can see, each message is written in various ways on different notecards in one group. Let's start with the first set of notecards." *[Read first message].*

[Potential to Persuade]: "First what we would like you to do is sort these notecards into three piles: most favorite, neutral and least favorite. Your piles do not have to even, you can put as many or as few as you would like in each pile." If you are part of a virtual presentation, please keep a notebook for review. *[Give participants time to do this]*

[Phrases Most Liked and Disliked]: "Next, mark any words or phrases on these messages that you really liked. Also mark any words or phrases that you really disliked. Culturally, are there words or passages that you liked, disliked, or need to be changed? You can mark as many as you want, you do not have to mark something on every message." *[Give participants time to do this]*

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[Reactance]: Third, we want you to look at all the messages one more time. Did any of these messages make you feel defensive, angry, annoyed, aggravated or irritated? Indicate this to us by making a note on the corner of these messages. If you have certain feeling towards the messages feel free to write them down on that note card or in your notebook. Culturally, are there words or passages that you liked, disliked, or need to be changed?" *[Give participants time to do this]*

"We will repeat this process with the next sets of notecards."

[Co-facilitator collects the messages and organizes messages on a wall/board (or virtually) where all participants can see, into commonly liked and disliked categories while participants work on the next sets of notecards.]

Semi-Structured Interview/FG

[Allow co-facilitator to finish organizing messages while starting discussion.]

"Thank you everyone for taking some time to read through those messages. Now we want to start a discussion around what everyone thought of these messages?" (be sure to include "think what this means culturally as well?").

[QUESTION 2] "Now let's draw our attention to the compiled messages on the board/wall (or virtual sharing). Overall, what are your feeling towards these specific messages?"

[Probes]

"Is there a particular message that stood out to you? Are there any cultural or ancestral items that need to be included or adapted?"

"Did you notice that the audience was different for these messages? What do you think about that?"

[If there's a tone of voice that sticks out, bring that to participant attention]

"We also framed these messages in different tones of voices: authoritative, empathetic and catchy. It seems like ____ tone of voice was most/least liked. What are your feelings/thoughts on that?" "Is this acceptable, culturally?"

[If there's a word or phrase that most people did not like, bring that to participant attention]

"We can also see on the board (or virtually) that most of you did not like and/or really liked these specific words/phrases: _____. Why is that?"

[If there's a message that had a strong reactance, bring that to participant attention]

"We've also noticed that most of you had strong feelings of anger or irritation towards _____ message. Can anyone explain more about why that message brought on those feelings?" "Are they culturally appropriate?"

[QUESTION 3] "So now looking at the messages, how would you rewrite or reword these messages?"

[allow participants time to each write 1-2 of their own text messages and share with the group.]

[QUESTION 4] "Now I want to gauge your feelings about personalized messages. How do you think it would make a difference, if any, if messages were to be personalized? Do you think it's necessary?"

"Culturally are these appropriate?"

[QUESTION 5] "Now I want to ask you a few questions about the delivery of these messages. If we were to send out all the messages at once, what time of the day and days of the week do you think would be best to deliver these messages? "Are these times culturally appropriate?"

[Probe]

"Think back to your own experiences receiving health messages (e.g., texts). When are you most likely to look and reflect at these messages? When are you most likely to ignore the message? Do you get annoyed when you receive too many messages? How many is too many?"

[QUESTION 6] "Do you feel this program could be used for other sports/athletic teams? If so, what would need to be added or changed?"

[QUESTION 5] "Overall how might other factors in history be influential on this overall proposed work? For example, racism, discrimination, historical traumas (forced removal, boarding schools).

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Conclusion

Thank you for participating in the focus group or interview today. Your input is very valuable to us and we will be using what we learned today to modify our current bank of health messages.

[End of focus group/individual interview]

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Appendix E. Study Demographics Questionnaire (Aim 1)

Study Demographics Survey



SSB: Lacrosse/Athletics

DEMOGRAPHICS			
DEMOGRAPHIC QUESTIONS - GENERAL			
Item	Survey Question	Response	Variable Label
1	What is your current age?	[type number]	AAGE
	STEM: In this section, we want to get some basic background information from you.		
2	Date of Birth	[MM/DD/YYYY]	ABIRTHDATE
3	Birth Sex	Male (0) Female (1)	ASEX
4	Gender Identity	Male (0) Female (1) Two-Spirit (2) Transgender (3) Other (4)	AGENDER
5	Sexual Orientation	Straight (0) Gay/Lesbian (1) Two-Spirit (2) Bisexual (3) Other (4) I prefer not to answer (99)	ASEXORIENT
6	Ethnic Background	Non-Hispanic/Latino (0) Hispanic/Latino (1)	AETHNIC
7	Racial Background (check all that apply)	American Indian (1) Alaska Native (2) First Nation (3) Metis (4) Inuit (5) Native Hawaiian or other Pacific Islander (6) Black or African American (7) Asian (8) Caucasian/White (9) Other: (10) (please specify): _____ (ARACE.10.TEXT2)	ARACE
8	Marital Status	Married (0) Living as married (1) Divorced (2) Widowed (3) Separated (4) Single, never been married (5)	AMARITAL
9	Combined household annual income	\$0- \$9,000 (0) \$10,000-\$14,999 (1) \$15,000-\$19,999 (2) \$20,000-\$34,999 (3) \$35,000-\$49,999 (4) \$50,000-\$74,999 (5) \$75,000-\$99,999 (6) \$200,000 or more (7)	AAINCOME

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10	Occupational status	Employed (0) Unemployed (1) Homemaker (2) Retired (3) Disabled (4) Other (5) (Specify) _____ (AOCCUPATION.5.TEXT2)	AOCCUPATION
11	How many people currently live in your home (include yourself)?	[type number]	APPLHOME
12	What is the primary source of your health care coverage?	A plan purchased through an employer or union (including plans purchased through another person's employer) (1) A plan that you or another family member buys on your own (2) Medicaid (primarily for people over age 65) or other state program (3) Medicare (4) TRICARE (formerly CHAMPUS), VA, or Military (5) Alaska Native, Indian Health Service, Tribal Health Service (6) Some other source (7)	AHEALTHCARE
DEMOGRAPHIC QUESTIONS - LANGUAGE			
1	[ONLY SHOW IF RACE = 1, 2, 3, 4, 5, or 6] What is your tribal language?	[type response]	ALANG1
2	[ONLY SHOW IF RACE = 1, 2, 3, 4, 5, or 6] How familiar are you with your tribal language?	Not familiar with tribal language (1) Somewhat familiar, but don't speak tribal language (2) Speak a little, but not well (3) Speak moderately well (4) Speak tribal language well (5)	ALANG2
3	Do you speak another language besides a tribal language or English?	Yes (1) No (0)	ALANG3
4	[ONLY SHOW IF ALANG3 = 1] What other languages do you speak besides a tribal language or English?	Spanish (1) Other (2) (Please specify name of the language you speak.) _____	ALANG4
DEMOGRAPHIC QUESTIONS - EDUCATION			
1	What is the highest level of education you have completed?	High School diploma (1) General Equivalency Degree (GED) (2) Vocational degree (3) Associate's degree (4) Bachelor's degree (5) Graduate or professional degree (6) None of the above (7)	ASELFDEGREE
2	What is the highest level of education your father or male caregiver completed?	Elementary (1) Junior high (2) High school non-graduate (3) High school graduate or GED (4) Some college, did not complete degree (5) Associate's degree (6) Bachelor's degree (7) Master's degree (8) Doctoral degree (9) Other (10) (Please specify) _____ (AFATHERDEGREE.TEXT) Don't Know (98)	AFATHERDEGREE

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3	What is the highest level of education your mother or female caregiver completed?	Elementary (1) Junior high (2) High school non-graduate (3) High school graduate or GED (4) Some college, did not complete degree (5) Associate's degree (6) Bachelor's degree (7) Master's degree (8) Doctoral degree (9) Other (10) (Please specify) _____ (AMOTHERDEGREE.TEXT) Don't Know (98)	AMOTHERDEGREE
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Demographics
THE REVISED MULTI-GROUP ETHNIC IDENTITY MEASURE (MEIM-R)

Item	Survey Question	Response	Variable Label
1	I have spent time trying to find out more about my ethnic group, such as its history, traditions, and customs.	Strongly disagree (1) Disagree (2) Neutral (3) Agree (4) Strongly Agree (5)	AMEIM-R1
2	I have a strong sense of belonging to my own ethnic group.		AMEIM-R2
3	I understand pretty well what my ethnic group membership means to me		AMEIM-R3
4	I have often done things that will help me understand my ethnic background better.		AMEIM-R4
5	I have often talked to other people in order to learn more about my ethnic group.		AMEIM-R5
6	I feel a strong attachment towards my own ethnic group.		AMEIM-R6

TRIBAL AFFILIATION

Item	Survey Question	Response	Variable Label
	[ONLY SHOW IF RACE = 1, 2, 3, 4, 5 or 6]		
1	How many tribal nations do you identify with?	One tribe (1) Two tribes (2) Three or more tribes (3)	ATA1
2	Which is the main tribe you identify with? Name of tribe _____	Fill in the blank	ATA2

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3	[ONLY SHOW IF ATA1 = 2 or 3] Which is the second tribe you identify with? _____	Fill in the blank	ATA3
4	Are you enrolled in any tribal nation?	No (0) Yes (1)	ATA4
5	[ONLY SHOW IF ATA5 = 1] In which tribal nation are you enrolled (name of tribal nation)? _____	Fill in the blank	ATA5
	STEM: You indicated that you most closely identify with the {RESPONSE:TA2}. If A represents yourself and B represents your tribal community please select the pair of circles that you feel best represents...		
6	how much you feel your beliefs match those you see in your community?	1 (1) 2 (2) 3 (3) 4 (4) 5 (5) 6 (6) 7 (7)	ATA6
7	how much of a match you feel there is between the cultural protocols that you use and those you see in your community?		ATA7
8	Being a part of my tribe is important to me.	Strongly disagree (1) Somewhat disagree (2) Neutral (3) Somewhat agree (4) Strongly agree (5)	ATA8
9	How often do you participate in tribal activities such as attending community gatherings, voting in tribal elections, etc.?	Daily (1) Weekly (2)	ATA9
10	How often do you participate in traditional ceremonies?	Monthly (3)	ATA10
11	How often do you participate in religious ceremonies or spiritual services?	A few times a year (4) Once a year (5)	ATA11
	STEM: Now we will ask some questions about how you think about your role in your Tribal community. A tribal community can be within an urban Indian setting, within your Tribal College setting, or within your home reservation or traditional lands. Please select the response that best fits your sense of how you fit within your tribal community.		
12	I know how to behave properly in my tribal community.		ATA12
13	I am able to behave properly in my tribal community.		ATA13
14	I am able to act in the ways tribal members expect me to act.		ATA14
15	When I act in the ways tribal members expect me to act, I feel a connection with others in my tribe(s).		ATA15
16	I feel like I fit in with my tribal community members by the way I behave.		ATA16
17	I am not sure how to behave around others in my tribe(s).		ATA17
18	I feel like I do not fit in with my tribal community members by the way I behave.	Strongly Disagree (1)	ATA18
19	I understand the way my tribal community defines family and other tribally-based relationships.	Somewhat disagree (2) Neither agree nor disagree (3)	ATA19
20	I am able to behave in appropriate ways in the relationships I have with other people in my tribal community.	Somewhat agree (4) Strongly agree (5)	ATA20
21	When I am with members of my tribal community...	I feel good. (1) I feel connected to my culture. (2) I feel like I am accepted. (3) I feel stressed. (4) I feel like I don't know my culture. (5) I feel like an outsider. (6)	ATA21

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Appendix F. Study Data Collection Instruments (Aim 2)

What year were you born? _____.

What is your birth sex? (circle one letter)

- a) Male
- b) Female

What is your gender identity? (circle one letter)

- a) Male
- b) Female
- c) Two-Spirit
- d) Transgender
- e) Other

What is your ethnic background? (circle one letter)

- a) Non-Hispanic/Latino
- b) Hispanic/Latino

What is your racial background? (circle one letter)

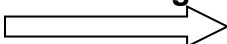
- a) American Indian
- b) Alaska Native
- c) First Nation
- d) Metis
- e) Inuit
- f) Native Hawaiian or other Pacific Islander
- g) Black or African American
- h) Asian
- i) Caucasian/White
- j) Other (please write down)_____

What is your tribal language? (Write answer)

How familiar are you with your tribal language? (circle one letter)

- a) Not familiar with tribal language
- b) Somewhat familiar, but don't speak tribal language
- c) Speak a little, but not well
- d) Speak moderately well
- e) Speak tribal language well

Do you speak another language besides tribal language or English? (circle one letter)

- a) Yes 
- b) No

What other languages do you speak besides a tribal language or English? (circle one letter)

- a) Spanish
- b) Other (please write answer)_____

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Thinking about members of your family living in this household, what is your combined annual income, meaning the total pre-tax income from all sources earned in the past year? (circle one letter)

- a) \$0 to \$9,999
- b) \$10,000 to \$14,999
- c) \$15,000 to \$19,999
- d) \$20,000 to \$34,999
- e) \$35,000 to \$49,999
- f) \$50,000 to \$74,999
- g) \$75,000 to \$99,999
- h) \$100,000 to \$199,999
- i) \$200,000 or more
- j) Decline to state

What is the highest grade or level of schooling you completed? (circle one letter)

- a) Less than 8 years
- b) 8 through 11 years
- c) 12 years or completed high school
- d) Post high school training other than college (vocational or technical)
- e) Some college
- f) College graduate
- g) Postgraduate

What is your marital status? (circle one letter)

- a) Married
- b) Living as married
- c) Divorced
- d) Widowed
- e) Separated
- f) Single, never been married

What is your current occupational status? (circle one letter)

- a) Employed
- b) Unemployed
- c) Homemaker
- d) Student
- e) Consulting/ gig work
- f) Retired
- g) Disabled
- h) Other (Specify) _____

Including yourself, how many people live in your household? (write number)

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Indigenous SIPin Evaluation Measures

Table 4. Variables Measured				
Variable	Assessment level	Instrument	Method	Timing
Primary outcome				
SSB intake	Participant	BEV-Q(1), BRFSS(2)	Survey	Base, 6
Secondary outcomes				
Dietary intake	Participant	24-hour recalls	Survey	Base, 6
Weight change (% relative to base)	Participant	Assessment Protocol	Measured Weight and Height	Base, 6
Historical trauma	Participant	Historical Losses Scale(3)	Survey	Base, 6
Cultural connectedness	Participant	Cultural connectedness scale(4)	Survey	Base, 6
Resilience	Participant	Connor-Davidson Resilience Scale (CD-RISC)(5) Sources of Strength Scale(6)	Survey	Base, 6
Process evaluation				
Participation rate (eligible/agreed)	Reservation, participant	Study form	Staff report	Base
Completion rate (proportion intervention received; (mean proportion of lessons attended)	Reservation, participant	Study form	Staff report	Post intervention
Fidelity	Interventionist	SIPsmartER fidelity measure(7)	Survey	Once during intervention, before lesson 3
Feasibility, acceptability, appropriateness	Participant	Weiner et al.(8)	Survey	Post intervention
Demographic information	Reservation, interventionist, participant	Study form, survey	Staff report, survey	Base

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Beverage Questionnaire (BEVQ-15)

Instructions:

In the past month, please indicate your response for each beverage type by marking an "X" in the bubble for "how often" and "how much each time".

Participant ID _____

1. Indicate how often you drank the following beverages, for example, if you drank 5 glasses of water per week, mark 4-6 times per week.

Date _____

2. Indicate the approximate amount of beverage you drank each time, for example, if you drank 1 cup of water each time, mark 1 cup under "how much each time".

3. Do not count beverages used in cooking or other preparations, such as milk in cereal.

4. Count milk added to tea and coffee in the *tea/coffee with cream beverage category* **NOT** in the milk categories.

Type of Beverage	HOW OFTEN (MARK ONE)							HOW MUCH EACH TIME (MARK ONE)				
	Never or less than 1 time per week (go to next beverage)	1 time per week	2-3 times per week	4-6 times per week	1 time per day	2+ times per day	3+ times per day	Less than 6 fl oz (3/4 cup)	8 fl oz (1 cup)	12 fl oz (1 1/2 cups)	16 fl oz (2 cups)	More than 20 fl oz (2 1/2 cups)
Water	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
100% Fruit Juice	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Sweetened Juice Beverage/Drink (fruit ades, lemonade, punch, Sunny Delight)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Whole Milk	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Reduced Fat Milk (2%)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Low Fat/Fat Free Milk (Skim, 1%, Buttermilk, Soy milk)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Soft Drinks, Regular	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Diet Soft Drinks/Artificially Sweetened Drinks (Crystal Light)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Sweetened Tea	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Tea or Coffee, with cream and/or sugar (includes non-dairy creamer)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Tea or Coffee, black, with/without artificial sweetener (no cream or sugar)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Beer, Ales, Wine Coolers, Non-alcoholic or Light Beer	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Hard Liquor (shots, rum, tequila, etc.)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Wine (red or white)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Energy & Sports Drinks (Red Bull, Rockstar, Gatorade, Powerade, etc.)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Other (list):	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Virginia Polytechnic Institute and State University, 2010.

SSB Intake: BRFSS

How often do you drink regular soda or pop that contains sugar? Do not include diet soda or diet pop. (write number)

___ times per week

About how often do you drink sweetened fruit drinks, such as Kool-aid, cranberry, lemonade, Hawaiian Punch, Hi-C, Minute Maid, Ocean Spray Cranberry Juice Cocktail, Snapple? Include fruit drinks you made at home and added sugar to. (write number)

___ times per week

On average, how often in the past month did you consume presweetened iced tea or tea you sweetened? (For example, Lipton, Honest Tea, tazo, Nestea, sweet tea in a restaurant or you made yourself) (circle one number)

1 Never or less than 1 per month

2 Between 1-4 per month

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- 3 Between 2-6 per week
- 4 One (1) per day
- 5 Two (2) per day
- 6 Three (3) per day
- 7 Four (4) per day or more

Dietary Intake: 24-hour recalls

Body Weight and Height

Anthropometry Data Collection Form

Date: _____

Check one:

- ☐ Baseline
☐ 6 months after enrollment

Data Collected By: _____

Participant ID# _____

Height ft inches
(to the nearest .25 inch)

Weight lbs

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Historical Losses Scale

“Now I would like to ask you about how you feel when you think about these losses.”

		Several times a day	Daily	Weekly	Monthly	Yearly or only at special times	Never	DK/REF
A	The loss of our land	1	2	3	4	5	6	9
B	The loss of our language	1	2	3	4	5	6	9
C	Losing our traditional spiritual ways	1	2	3	4	5	6	9
D	The loss of our family ties because of boarding Schools	1	2	3	4	5	6	9
E	The loss of families from the reservation to government relocation	1	2	3	4	5	6	9
F	The loss of self respect from poor treatment by government officials	1	2	3	4	5	6	9
G	The loss of trust in whites from broken treaties	1	2	3	4	5	6	9
H	Losing our culture	1	2	3	4	5	6	9
I	The losses from the effects of alcoholism on our people	1	2	3	4	5	6	9
J	Loss of respect by our children and grandchildren for elders	1	2	3	4	5	6	9
K	Loss of our people through early death	1	2	3	4	5	6	9
L	Loss of respect by our children for	1	2	3	4	5	6	9

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Cultural Connectedness

1. I plan on trying to find out more about my [Aboriginal/FNMI] culture, such as its history, traditions, and customs.^a
2. I have spent time trying to find out more about being [Aboriginal/FNMI], such as its history, traditions and customs.^b
3. I have a strong sense of belonging to my [Aboriginal/FNMI] community or Nation.^b
4. I have done things that will help me understand my [Aboriginal/FNMI] background better.^b
5. I have talked to other people in order to learn more about being [Aboriginal/FNMI].^b
6. When I learn something about my [Aboriginal/FNMI culture], I will ask someone more about it later.^b
7. I feel a strong attachment towards my [Aboriginal/FNMI] community or Nation.^b
8. If a traditional person, Elder, or Clan Mother spoke to me about being [Aboriginal/FNMI], I would listen to them carefully.^b
9. I feel a strong connection to my ancestors.^b
10. Being [Aboriginal/FNMI] means I sometimes have a different way of looking at the world.^b
11. It is important to me that I know my [Aboriginal/FNMI] language.^b

Traditions (11 items)

1. I can understand some of my [Aboriginal/FNMI] language.^a
2. I use tobacco for guidance.^a
3. I have participated in a cultural ceremony (examples: Sweatlodge, Moon Ceremony, Sundance, Longhouse, Feast or Giveaway).^a
4. I have helped prepare for a cultural ceremony (examples: Sweatlodge, Moon Ceremony, Sundance, Longhouse, Feast or Giveaway).^a
5. I have offered food or feasted someone/something for a cultural reason.^a
6. Someone in my family or someone I am close with attends cultural ceremonies (examples: Sweatlodge, Moon Ceremony, Sundance, Longhouse, Feast or Giveaway).^a
7. I plan on attending a cultural ceremony in the future (examples: Sweatlodge, Moon Ceremony, Sundance, Longhouse, Feast or Giveaway).^a
8. I have a traditional person, Elder or Clan Mother who I talk to.^a
9. How often do you make tobacco offerings for cultural purposes? ^c
10. How often do you use sage, sweetgrass, or cedar in any way or form? ^c
11. How often does someone in your family or someone you are close with use sage, sweetgrass, or cedar in any way or form? ^c

Spirituality (7 items)

1. I know my cultural/spirit name.^a
2. In certain situations, I believe things like animals and rocks have a spirit like [Aboriginal/FNMI] people.^a
3. The eagle feather has a lot of meaning to me.^b
4. When I am physically ill, I look to my [Aboriginal/FNMI] culture for help.^b
5. When I am overwhelmed with my emotions, I look to my [Aboriginal/FNMI] culture for help.^b
6. When I need to make a decision about something, I look to my [Aboriginal/FNMI] culture for help.^b
7. When I am feeling spiritually disconnected, I look to my [Aboriginal/FNMI] culture for help.^b

^a No or Yes response format. ^b Strongly disagree, Disagree, Do not agree or disagree, Agree, Strongly disagree response format.

^c Never, Once/twice in the last year, Every month, Every week, Every day response format.

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Connor-Davidson Resilience Scale (CD-RISC)

The CD-RISC contains 25 items, all of which carry a 5-point range of responses, as follows: not true at all (0), rarely true (1), sometimes true (2), often true (3), and true nearly all of the time (4). The scale is rated based on how the subject has felt over the past month. The total score ranges from 0–100, with higher scores reflecting greater resilience.

Item no.	Description
1	Able to adapt to change
2	Close and secure relationships
3	Sometimes fate or God can help
4	Can deal with whatever comes
5	Past success gives confidence for new challenge
6	See the humorous side of things
7	Coping with stress strengthens
8	Tend to bounce back after illness or hardship
9	Things happen for a reason
10	Best effort no matter what
11	You can achieve your goals
12	When things look hopeless, I don't give up
13	Know where to turn for help
14	Under pressure, focus and think clearly
15	Prefer to take the lead in problem solving
16	Not easily discouraged by failure
17	Think of self as strong person
18	Make unpopular or difficult decisions
19	Can handle unpleasant feelings
20	Have to act on a hunch
21	Strong sense of purpose
22	In control of your life
23	I like challenges
24	You work to attain your goals
25	Pride in your achievements

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Sources of Strength Scale

Items were rated on a Likert scale anchored by 1 (*strongly disagree*) and 10 (*strongly agree*).

Variables	<i>M</i>	<i>SD</i>	<i>Measures</i>
Q1: I feel my family cares about me, spends time with me, and is a strong support for me.	8.54	1.95	Social Support
Q2: I feel I have healthy friends/peer group that makes good decisions/stays out of trouble.	7.33	2.01	Social Support
Q3: I feel I have good caring relationships with adults who truly care about me.	8.13	2.10	Social Support
Q4: I feel I keep involved in healthy activities like sports, music, art, teams, organizations.	9.04	1.52	Healthy Involvement
Q5: I feel I am regularly involved in helping others, sharing generosity, and have leadership opportunities.	7.96	1.75	Healthy Involvement

Variables	<i>M</i>	<i>SD</i>	<i>Measures</i>
Q6: I feel I have healthy beliefs and that I actively develop my faith, spirituality, or culture.	7.98	2.09	Personal Beliefs
Q7: I feel I have good access to a counselor, support group, or other mental health services.	7.40	2.20	Access to Services
Q8: I feel I have good access to a doctor, nurse, or other medical help if I was ill, injured, or needed medicine.	7.92	2.19	Access to Services
Q9: I participate in Leadership programs at my school.	7.25	2.90	Leadership
Q10: I am working on personal wellness and positive changes in my behavior.	7.75	2.46	Personal Beliefs
Q11: I take time to volunteer at school or in my community.	7.10	2.65	Leadership

Revised Multi-group ethnic identity measure (MEIM-R)

1. I have spent time trying to find out more about my ethnic group, such as its history, traditions, and customs.
2. I have a strong sense of belonging to my own ethnic group.
3. I understand pretty well what my ethnic group membership means to me
4. I have often done things that will help me understand my ethnic background better.
5. I have often talked to other people in order to learn more about my ethnic group.
6. I feel a strong attachment towards my own ethnic group.

Response Options: Strongly disagree (1); Disagree (2); Neutral (3); Agree (4); Strongly Agree (5)

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Feasibility, acceptability, and appropriateness (Weiner et al.)

Feasibility of Intervention Measure (FIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. (INSERT INTERVENTION) seems implementable.	①	②	③	④	⑤
2. (INSERT INTERVENTION) seems possible.	①	②	③	④	⑤
3. (INSERT INTERVENTION) seems doable.	①	②	③	④	⑤
4. (INSERT INTERVENTION) seems easy to use.	①	②	③	④	⑤

Acceptability of Intervention Measure (AIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. (INSERT INTERVENTION) meets my approval.	①	②	③	④	⑤
2. (INSERT INTERVENTION) is appealing to me.	①	②	③	④	⑤
3. I like (INSERT INTERVENTION).	①	②	③	④	⑤
4. I welcome (INSERT INTERVENTION).	①	②	③	④	⑤

Intervention Appropriateness Measure (IAM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. (INSERT INTERVENTION) seems fitting.	①	②	③	④	⑤
2. (INSERT INTERVENTION) seems suitable.	①	②	③	④	⑤
3. (INSERT INTERVENTION) seems applicable.	①	②	③	④	⑤
4. (INSERT INTERVENTION) seems like a good match.	①	②	③	④	⑤

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Save these materials for your dietary recall.
[NAME] from Roswell will call you to do a dietary recall.

They will call you from one of these phone numbers: (716) XXX-XXXX or “Roswell Park Comprehensive Cancer Care” (716) 845-2300 so please answer your phone when they call.

You will be given a \$[AMOUNT] Gift Card for each dietary recall.

Someone will call you:

Call 1: _____

Call 2: _____

Call 3: _____

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24-Hour Recalls

What's a 24-Hour Recall?



24-hour recalls are a way of figuring out what you usually eat and drink. We will get this information through talking to you on the telephone, where we will ask you to remember what you ate and drank during the previous day.

The telephone recalls will occur on 3 separate days at the start of the study, and 3 separate days at the end of the study. The days will be selected at random so that weekdays (Monday through Thursday) and one weekend day (Friday through Sunday) is included. This will help us figure out your *average* diet.

Scheduling the Calls

A person from Roswell Park Cancer Institute, Buffalo, NY will be calling you to do the recalls. They will call you during the times you said would work best with your schedule when you signed up to be a part of the study. At this time, they will call and ask you for details of **everything** -- all foods and liquids (including water) -- that you ate or drank during the past 24 hours *from midnight to midnight of the previous day*.

The person will ask you the amount you actually ate or drank, not how much was put into the dish, cup, or bowl. Please use the "**Food Amounts Booklet**" that we sent you with this sheet. The following tips will also help you estimate how much you eat and drink.



Measuring Tips

Use measuring cups and spoons to help you tell the Roswell person the exact amount you ate or drank.



Instead of telling the Roswell person you had breakfast cereal, give more details like: 1 cup of wheat flakes with 1/2 cup of lowfat milk, and 1/2 of a large (8-inch) banana.

- Measure the volume of dishes, bowls, cups, and glasses that you use a lot. This will help you to figure out and report the correct volume of food/drink each time you use that container.
- For pieces of food that do not fit into a cup or spoon, describe the size using the "**Food Amounts Booklet**".

For example, 1 corn tortilla (6 inches across), and 1 cube of cheese (2" long x 1" wide x 1/2" high). You can use weight or dimensions for reporting meat, fish, poultry, cheese, pizza, and baked goods. Include thickness, length, and width of food using a ruler. Indicate if the weight was obtained before or after cooking.

Be Specific. When naming the food or drink that you ate/drank, give the Roswell person details. For example, if you ate meat, details such as the part eaten are important. If you ate chicken, tell the person whether it was from the thigh or breast, or if it was white or dark meat.

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Brand Names & Labels. Brand names of prepared foods are very useful for the Roswell person, as are labels from the prepared foods you have eaten.

Mixed Foods. Be prepared to tell the Roswell person what is in a mixed food. For example, rather than just saying 1 cup of stew, do your best to give the amount of each major item in the stew, such as 1/4 cup stewed beef, 1/4 cup potato, 1/4 cup carrot, 1/4 cup gravy. If you made a dish at home, report the recipe used including all ingredients, and the number of servings from the recipe or what portion of the total you actually ate.

Preparation Method. It is as baked, boiled, broiled, in shortening, no flour or



also important for you to describe how the food was cooked, such as fried, breaded and fried. For example, one chicken drumstick (fried batter).

Add-Ons. Remember to margarine, mustard, jelly,

tell your Roswell person the little things added to foods like butter, sugar, gravy, or salad dressing.

Nonfat Items. Don't forget to report nonfat items. Just because they are nonfat does not mean they are not important to include.

Time & Place. The Roswell person will ask you to say about what time the food or drink was eaten or drank, and whether it was eaten at a meal or a snack. It is also very helpful if you can say where the food or drink was eaten/drank, for example at home, work, school, restaurant, store, etc. *For example, at 2:00 PM, I ate a snack at home. The snack was 2 tablespoons of raisins and 8 whole-grain crackers (2-inch diameter).*

Thank you for being a part of this very important study. We look forward to talking with you.

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Indigenous SIPin Program Satisfaction

We are interested in learning about your experience with Indigenous SIPin so we can help make the program better for other people. We will ask you to rate different parts of the program. All of your opinions are important to us. Please circle only one number for each question.

These first questions ask about your experience with the SIPin group classes.

1. How satisfied were you with how the group classes were organized?

Very Unsatisfied	Somewhat Unsatisfied	Neither Unsatisfied or Satisfied	Somewhat Satisfied	Very Satisfied
[1]	[2]	[3]	[4]	[5]

2. The group classes provided me with useful information to help me drink fewer sugary drinks.

Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Strongly Agree
[1]	[2]	[3]	[4]	[5]

3. How satisfied were you with the type of activities presented in the group classes?

Very Unsatisfied	Somewhat Unsatisfied	Neither Unsatisfied or Satisfied	Somewhat Satisfied	Very Satisfied
[1]	[2]	[3]	[4]	[5]

4. I was satisfied with the number of group classes.

Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Strongly Agree
[1]	[2]	[3]	[4]	[5]

5. Overall, how satisfied were you with how group classes?

Very Unsatisfied	Somewhat Unsatisfied	Neither Unsatisfied or Satisfied	Somewhat Satisfied	Very Satisfied
[1]	[2]	[3]	[4]	[5]

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These next questions ask about your experience with the SIPin text messages.

6. The text messages provided me with useful strategies to help me drink fewer sugary drinks.

Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Strongly Agree
[1]	[2]	[3]	[4]	[5]

7. The text message system was easy to use.

Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Strongly Agree
[1]	[2]	[3]	[4]	[5]

8. The text messages were personalized for my goals.

Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Strongly Agree
[1]	[2]	[3]	[4]	[5]

9. I was satisfied with the number of text messages.

Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Strongly Agree
[1]	[2]	[3]	[4]	[5]

10. Overall, how satisfied were you with the text messages?

Very Unsatisfied	Somewhat Unsatisfied	Neither Unsatisfied or Satisfied	Somewhat Satisfied	Very Satisfied
[1]	[2]	[3]	[4]	[5]

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These next questions ask about your overall experience with the SIPin program.

11. How satisfied were you with the access and availability of the research staff?

Very Unsatisfied	Somewhat Unsatisfied	Neither Unsatisfied or Satisfied	Somewhat Satisfied	Very Satisfied
[1]	[2]	[3]	[4]	[5]

12. How satisfied were you with the handouts and materials?

Very Unsatisfied	Somewhat Unsatisfied	Neither Unsatisfied or Satisfied	Somewhat Satisfied	Very Satisfied
[1]	[2]	[3]	[4]	[5]

13. How satisfied were you with the videos that recapped the group class lessons?

Very Unsatisfied	Somewhat Unsatisfied	Neither Unsatisfied or Satisfied	Somewhat Satisfied	Very Satisfied
[1]	[2]	[3]	[4]	[5]

14. Overall, how satisfied were you with your experience in the *Indigenous SIPin*?

Very Unsatisfied	Somewhat Unsatisfied	Neither Unsatisfied or Satisfied	Somewhat Satisfied	Very Satisfied
[1]	[2]	[3]	[4]	[5]

15. Tell me how your drinking habits changed since starting Indigenous SIPin.

16. Is there anything else you would like to share about your experience in the Indigenous SIPin program?

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Appendix G. Recruitment Flyer (Aim 2)

TUSCARORA ATHLETICS INDIGENOUS SIP IN

6-Month Program to drink healthier drinks

- Eligible to ages 18+
- And must drink at least 200 calories of sugary drinks [2 cans of soda] a day

All participants will be given two assessments, one before the program and one after. Each participant will receive a \$25 gift card at the first assessment, and a \$50 gift card at the second assessment.

**Contact Coach Randy Chrysler
or Corinne Abrams cell: 716-800-9417
email: corinne.abrams@roswellpark.org**

ROSWELL PARK
COMPREHENSIVE CANCER CENTER

**CENTER FOR
INDIGENOUS
CANCER
RESEARCH**

**NIH Grant funded by National Institute of Nursing
Research Grant Number: 1R56NR019498-01**

**A wellness program wrapped around athletics and lacrosse to
learn more about reconnecting with ancestral drinks and
healthy beverage consumption**

**DATE:
TIME:
LOCATION:**

Roswell Park Protocol Number: I 810620

Appendix H. Letter of Support

TUSCARORA ATHLETICS

March 2, 2022

Re: Indigenous SIPin Lacrosse

Greetings,

On behalf of the Tuscarora Athletics nonprofit organization, we provide this letter of support and commitment to the Roswell Park Center for Indigenous Cancer Research (CICR). Our board agrees to participate as a collaborative partner in with CICR's sugarsweetened beverages (SSB) intervention, titled "Indigenous SIPin."

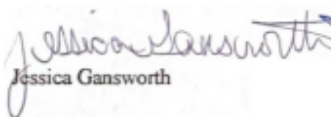
The proposed program aligns with our nonprofit's goals to build upon the strengths of our people by focusing on the power of the good mind, health, wellness, education and our connections to the land for our future generations. The organizational board is in full support of the collaborative efforts between the Tuscarora Athletics nonprofit and Roswell Park's Center for Indigenous Cancer Research. As part of the program, Tuscarora Athletics will create and implement a lacrosse program with multiple participants, encourage participation in the program, and structure the timing and dates to align with the intervention program.

Our organization's vision is to provide access to a healthy lifestyle through athletics, we do this to address the many health issues within our communities. We believe the collaborative efforts could increase the Native American lacrosse player participation in needed health education programs.

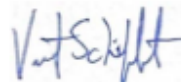
Nya:weh (thank you) for your time. If you have any questions regarding this correspondence, please contact the Jessica Gansworth, at (716) 812-0935.

Respectfully,

The Tuscarora Athletics Board Members


Jessica Gansworth


Randy Chrysler


Vince Schiffert


Clorissa Yellow


Maurice Yellow

Appendix I. SIPin Lesson Plan Crosswalk

SIPin Lesson Plan Crosswalk								
		handout/worksheet is complete	handout/worksheet is drafted	handout/worksheet needs to be created				
Timeline	Class #	Participant Learning Goal	Key Teachings	Lesson Plan	Learning Tools, Worksheets, and Handouts	In person lesson	Task	Text messages
Month 1`	Class 1	Identify reasons for reducing sugary drinks from diet	How can we apply the clean and dirty rivers to the way we live our lives.	1.1 Describe how the Clean and Dirty Rivers relate to the Good Mind.	Clean and Dirty River Diagram		Create a personal action plan	Education message uniform for all participants: "Hi [name], welcome to [name of program]! Over the next several months you will get about 2 text messages per week to help support you in reaching your sugary drink goals. People who track their sugary drinks and develop personal action plans are more likely to reach their goals. These tools allow us clearly monitor our sugary drinks, say why we want to make changes, and discover how to overcome any barriers."
The Clean and Dirty River and Principles of Indigenous Living				1.2 Understand how sugary drinks relate to the Clean and Dirty Rivers.	Personal Action Plan			
				1.3 State why they want to drink fewer dirty river/sugary drinks.				

1.4 Complete the 'Reasons why I want to drink fewer dirty river drinks' part of their personal action plan.

Class 2	What are clean and dirty river drinks	What are the benefits of clean river drinks	2.1 Distinguish between sugary and non-sugary drinks.	What am I drinking?	Revise personal action plan	Education message uniform for all participants: "Look around house see what drinks you have. Which drinks are clean river drinks? Which drinks are dirty river drinks? Have more clean river drinks in your home."
Clean and Dirty River Drinks		What are the negative health effects of dirty river drinks	2.2 Identify benefits of drinking clean river drinks like water	Clean and Dirty River Drinks Handout		
		Which drinks are dirty river drinks?	2.3 Identify detriments of drinking sugary/dirty river drinks	Health Risks worksheet (needs to be adapted to emphasize benefit of water)		
				Sugary drink examples (at least 5 different bottles and cans of Non-sugary drink examples (e.g. water bottles of difference sizes, flavored water)		

Class 3	Recognize that they drink too many dirty river drinks	How to know how much dirty river drinks you are drinking and keep track of dirty river drinks so you know when you're making progress	3.1 Recall dirty river/sugary drink recommendations.	Sugary drink examples (at least 5 different bottles and cans of sugary drinks; include sugar-added fruit drinks and energy drinks and sports drinks)	Set goals for sugary drink intake using calculated sugar content	Education message uniform for all participants: Hi [name], it's [name of program]. Let's start with a quick, 2 question check in. When you think about sugary drinks remember to include regular soda/pop, fruit-flavored drinks, energy drinks, sports drinks, sweet coffee and sweet tea, and flavored milk drinks.
Training techniques for a Clean River	Learn about portion sizes	Learn how to keep track using their drink diaries	3.2 Calculate their current dirty river/sugary drink intake. 3.3 Recognize that they drink too many dirty river/sugary drinks. 3.4 Refine their personal action plan and set goals to reduce their dirty river/sugary drink intake 3.5 Accurately track their daily dirty river/sugary drink intake.	Non-sugary drink examples (e.g. water bottles of difference sizes, flavored water) What am I drinking worksheet (needs to be adapted) Handout based on Jamie's slides that go over how to calculate total sugar drink ounces Drink Diaries	Complete drink diary for the week	On a typical day last week, about how many ounces of sugary drinks did you have <u>each day</u> ? 1- [I did not drink any sugary drinks last week] 2- [Less than 8 ounces each day] 3- [About 9-24 ounces each day] 4- [About 25-32 ounces each day] 5- [About 33-49 ounces each day] 6- [More than 50 ounces each day]

Education message uniform for all participants:
 "It can be difficult to track your sugary drinks. Sugary drinks come in many different sizes. Yet, as a rule of thumb, cans are typically 12 ounces and larger cans and bottles are usually 16-20 ounces. Refer to the label for an exact number and tally up your daily total ounces of sugary drinks."
 "

Class 4	Identify personal barriers and possible strategies to meet these barriers	There are barriers to making healthy changes.	4.1 Describe barriers/obstacles to drinking fewer dirty river/sugary drinks.	Clean and Dirty River Diagram	Revise Personal Action Plan	Education message uniform for all participants: Hi [name], it's [name of program]. Let's start with a quick, 2 question check in. When you think about sugary drinks remember to include regular soda/pop, fruit-flavored drinks, energy drinks, sports drinks, sweet coffee and sweet tea, and flavored milk drinks.	
The Four Baskets along the River		We can use culturally-based strategies to meet these barriers	4.2 Describe the four baskets	Barrier/Strategy Cards	Complete Drink Diary for the week	Education message uniform for all participants: On a typical day last week, about how many ounces of sugary drinks did you have each day?	
			4.3 Select which baskets would be most helpful for them to overcome their identified obstacles.	Personal Action Plan		1- [I did not drink any sugary drinks last week]	

4.4 Refine their personal action plan to reduce their dirty river/sugary drink intake to include obstacles and strategies.

Drink Diaries

Handout based on Jamie's slides that go over how to calculate total sugar drink ounces

2- [Less than 8 ounces each day]

3- [About 9-24 ounces each day]

4- [About 25-32 ounces each day]

5- [About 33-49 ounces each day]

6- [More than 50 ounces each day]

What tips would you like in the coming weeks?

1- [Basket 1: Building routine]

2- [Basket 2: Feeling good]

3- [Basket 3: Healthy Bodies]

4- [Basket 4: Staying Hydrated]

Insert Branch Logic
Personalized strategy message: Based on response from Week 4
Got it! You will now receive these tips over the next few weeks.

Insert Branch Logic.

Class 5	Choose clean river drinks like water to feel good physically, mentally, and spiritually	Dirty river drinks taste good but they don't help you feel good	5.1 List the tools in the "Feeling Good" Basket	Non-sugary drink examples (e.g. water bottles of difference sizes, flavored water)	Complete drink diary	Building Routine: - "Water is a gift from the creator. Share that gift with family and friends."
Feeling Good		Water is a gift from the creator that has everything you need (including electrolytes) to help you feel good physically, mentally, and spiritually	5.2 Recall sugary drink recommendations.	Sugary drink examples (at least 5 different bottles and cans of sugary drinks; include sugar-added fruit drinks and energy drinks and sports drinks)		Feeling Good: - "Give your taste buds time to adapt to sugar-free drinks."
		Drinking water is a way to stay connected with one's heritage	5.3 Review portion sizes	Personal Action Plan		Healthy Bodies: - "Limiting sugary drinks may promote more energy."
		Give yourself time to adapt to clean river drinks	5.4 Revise their personal action plan to reduce their sugary drink intake, including goals and strategies.	Drink Diaries		Staying Hydrated: - "If you're concerned about the cost of drinking more water, also think about the long-term investment in your health that drinking more water offers."

It is important
to respect sugar
and not drink
too much; it is
important to
respect water

Barrier/Strategy Cards

Education message uniform
for all participants:
"Remember, try your best to
limit your sugary drink intake
to just 8oz or less per day."

-INSERT INFOGRAPHIC WITH
MESSAGE-

Month 2	Class 6	By building a routine around non-sugary drinks, it's easier to avoid sugar sweetened drinks.	Strategies to make positive change a routine	6.1 List the tools in the "Building Routine" Basket	Personal Action Plan (needs to be adapted)	Complete drink diary
	Building Routine			6.2. Calculate their current sugary drink intake.	Drink Diaries	Personalized strategy message: Based on response from Week 2
				6.3. Accurately track their daily sugary drink intake	Barrier/strategy cards	Building Routine: - "Changing what you drink takes time. Be patient when you experience challenges in your wellness journey." Feeling Good: "Make a connection to your ancestral roots by drinking more water."
				6.4. Revise their personal action plan to reduce their sugary drink intake, including goals and strategies.	Handout based on Jamie's slides that go over how to calculate total sugary drink ounces for the week	Healthy Bodies: "Instead of getting your energy from sugary drinks, try boosting your energy by getting enough sleep when you can." Staying Hydrated: "Talk to your friends and family about how much money you are saving by not buying sugary drinks."

Education message uniform for all participants:
 "Writing down and periodically revisiting your reasons for drinking fewer sugary drinks may be a helpful daily reminder."

Class 7	Reinforce understanding of what has been covered in the previous 6 classes: clean and dirty river and the relationship between sugary drinks and healthy lifestyle	What does a clean river look like and how do we get there as a community?	7.1. Fine-tune their knowledge of knowing what clean and dirty river drinks are; national sugary drink recommendations; portion sizes; and how to track their daily sugar intake	Provide any replacement worksheets they request	Complete drink diary
How is your river- Checking in		What have you learned so far, and what do you need to learn to get to that clean river?	7.2. Discuss how their action plan is going		Hi [name], it's [name of program]. Let's start with a quick, 2 question check in. When you think about sugary drinks remember to include regular soda/pop, fruit-flavored drinks, energy drinks, sports drinks, sweet coffee and sweet tea, and flavored milk drinks. On a typical day last week, about how many ounces of sugary drinks did you have <u>each day</u>? 1- [I did not drink any sugary drinks last week] 2- [Less than 8 ounces each day] 3- [About 9-24 ounces each day] 4- [About 25-32 ounces each day]

5- [About 33-49 ounces each day]

6- [More than 50 ounces each day]

****Participants receive 1 of 4 feedback message based on last weeks and this week's intake (See Rules below)**

- Meeting Goal

- o Congrats! You drank little to no sugary drinks last week.

- You are on your way to meeting your health goals.

- Keep up the awesome work!

- What tips would like in the coming weeks?

1- [Basket 1: Building routine]

2- [Basket 2: Feeling good]

3- [Basket 3: Healthy Bodies]

4- [Basket 4: Staying Hydrated]

Got it! You will now receive these tips over the next few weeks.

- Reduced but not meeting goal

- o You've reduced how much you are drinking from last time, nice! Keep working to make small changes. What tips would like in the coming weeks?

Personalized strategy message: Based on response from Week 7

1- [Basket 1: Building routine]

2- [Basket 2: Feeling good]

3- [Basket 3: Healthy Bodies]

4- [Basket 4: Staying Hydrated]

Got it! You will now receive these tips over the next few weeks.

- Maintained but not meeting goal

o You maintained how much you are drinking. Keep making small changes towards healthy drink choices! What tips would like in the coming weeks?

Personalized strategy message: Based on response from Week 7

1- [Basket 1: Building routine]

2- [Basket 2: Feeling good]

3- [Basket 3: Healthy Bodies]

4- [Basket 4: Staying Hydrated]

Got it! You will now receive these tips over the next few weeks.

- Increased

o It looks like you have increased your intake from last time. Don't worry, slip-ups happen! Think about your barriers and plan to get on track with healthy drink choices. What tips would like in the coming weeks?

Personalized strategy message: Based on response from Week 7

1- [Basket 1: Building routine]
2- [Basket 2: Feeling good]
3- [Basket 3: Healthy Bodies]
4- [Basket 4: Staying Hydrated]
Got it! You will now receive these tips over the next few weeks.

Class 8	The best hydration comes from clean river drinks like water	True hydration will hydrate your body and keep your energy up in the long-term	8.1 List tools from the 'Staying Hydrated' basket that they can use to meet their sugary drink goals	Personal Action Plan	Complete drink diary	Personalized strategy message: Based on response from Week 6
Staying Hydrated		True hydration comes from clean river drinks		Drink Diaries		Building Routine: "On your next grocery shopping trip, buy half the number of sugary drinks you normally buy."

Feeling Good: To help you reduce the number of sugary drinks you drink but still get the taste you crave, try diluting your sugary drink with ice or water.”

Healthy Bodies: “Instead of getting your energy from sugary drinks, try exercising, like going for a quick walk.”

Staying Hydrated: “Use the money you save from drinking water instead of sugary drinks to do things with your family.”

Education message uniform for all participants

“Nearly all store-bought sugary drinks have a Nutrition Facts label. Don’t forget to glance at the label to determine how much sugar is in your drink.”

-INSERT INFOGRAPHIC-

Class 9	What to look for in a label	Understanding what is on a food label will help a person make decisions about the drinks in the store.	9.1 Review the Staying Hydrated Basket.	PPT slides (participant version)	Complete drink diary	Personalized strategy message: Based on response from Week 6

**Staying
Hydrated**

Learning how and where to find and make drinks without sugar is part of living a healthy and balanced life, which will move a person toward the clean river.

It is good to know the difference between a hydrated body and a body that has been fed sugar and additives. Staying hydrated is part of knowing your body, knowing what your body needs, and knowing what your body doesn't need.

9.2. Analyze food labels to determine serving size, ingredients, calories, and grams of sugar.

Reading a food label
handout

Sugary drink
comparison handout

drink ranking

personal action plan

drink diaries

Building Routine: - "It can be hard to find non-sugary drinks in the house. Rearrange your fridge so your family sees water (bottles) when they open it."

Feeling Good: "Find a non-sugary drink that is like your favorite type of sugary drink. Look for sugar-free drinks that have fizz."

Healthy Bodies: "The best way to stay hydrated as an athlete is to drink the ancestral source of water."

Staying Hydrated: "Drinking water instead of sugary drinks will save you money and keep you strong."

		Education message uniform for all participants "Many beverage companies aim to sell products that are known to be harmful. They also use marketing tricks to get you to buy more sugary drinks. See if you can spot these tricks."	
Class 10		Presentation	Review diary, continue to complete drink diary
Healthy Bodies	Healthy bodies are made stronger when a person uses fuels provided by the Creator or those found in nature Flavor of traditional drinks is important, find a way to make drinks without sugar taste good for you	Handout Log	Hi [name], it's [name of program]. Let's start with a quick, 2 question check in. When you think about sugary drinks remember to include regular soda/pop, fruit-flavored drinks, energy drinks, sports drinks, sweet coffee and sweet tea, and flavored milk drinks. On a typical day last week, about how many ounces of sugary drinks did you have <u>each day</u> ? 1- [I did not drink any sugary drinks last week]

Flavor of
traditional
drinks is
important, find
a way to make
drinks without
sugar taste
good for you

2- [Less than 8 ounces each
day]

Healthy bodies
are much like
our larger
environment-
when we
pollute the
environment, it
creates
problems for
everything,
from the
smallest insects
to the fish who
feed on those
insects, and so
on.

3- [About 9-24 ounces each
day]

4- [About 25-32 ounces each
day]

5- [About 33-49 ounces each
day]

6- [More than 50 ounces each
day]

****Participants receive 1 of 4
feedback message based on
last weeks and this week's
intake (See Rules below)**

- Meeting Goal

o Congrats! You drank little to no sugary drinks last week. You are on your way to meeting your health goals. Keep up the awesome work! What tips would like in the coming weeks?

1- [Basket 1: Building routine]

2- [Basket 2: Feeling good]

3- [Basket 3: Healthy Bodies]

4- [Basket 4: Staying Hydrated]

Got it! You will now receive these tips over the next few weeks.

- Reduced but not meeting goal

o You've reduced how much you are drinking from last time, nice! Keep working to make small changes. What tips would like in the coming weeks?

Personalized strategy message: Based on response from Week 7

1- [Basket 1: Building routine]

2- [Basket 2: Feeling good]

3- [Basket 3: Healthy Bodies]

4- [Basket 4: Staying Hydrated]

Got it! You will now receive these tips over the next few weeks.

- Maintained but not meeting goal

o You maintained how much you are drinking. Keep making small changes towards healthy drink choices! What tips would like in the coming weeks?

Personalized strategy message: Based on response from Week 7

1- [Basket 1: Building routine]

2- [Basket 2: Feeling good]

3- [Basket 3: Healthy Bodies]

4- [Basket 4: Staying Hydrated]

Got it! You will now receive these tips over the next few weeks.

- Increased

o It looks like you have increased your intake from last time. Don't worry, slip-ups happen! Think about your barriers and plan to get on track with healthy drink choices. What tips would like in the coming weeks?

Personalized strategy message: Based on response from Week 7

1- [Basket 1: Building routine]

2- [Basket 2: Feeling good]
 3- [Basket 3: Healthy Bodies]
 4- [Basket 4: Staying Hydrated]
 Got it! You will now receive these tips over the next few weeks.

Month 3	Class 11	Setting new goals and identifying areas where they are experiencing personal costs due to drinking sugary drinks	There are many costs that people pay when they consume sugary beverages.	11.1	Recognize the financial costs associated with drinking sugary drinks.	Presentation	NA_SSB_Lesson11_LessonPlan_3.9.22.docx	Sugary Drinks Savings Worksheet
	Healthy Bodies		Some of the costs are to health, others are just from buying the drinks	11.2	Estimate how much money they have potentially saved by reducing intake of sugary drinks	Handout Log		
								Building Routine: "When out with your friends, you may be worried that only sugary drinks will be available. Reconnect with the ancestral source of water and invite your friends to try it with you." Feeling Good: "Remember, it's okay to enjoy sugary drinks once in a while, just make sure it's not your everyday drink." Healthy Bodies: "Observe how you feel after drinking water vs. sugary drinks. You may find water offers improved energy without the sugar crash."

Staying Hydrated: “Compare the cost of drinking sugary drinks vs. drinking water every week.”

Education message uniform for all participants:
“With the money you have saved by limiting sugary drinks, brainstorm ways you can reinvest that money in your personal health or the health of your family.”

Class 12	Make a plan for maintaining a clean river	Maintaining a clean river	12.1 Sugary drink lapse Presentation	NA SSB Lesson 12 Lesson Plan 3.9.22.docx
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Personalized strategy message based on week 10

The Clean River		Celebrate the big and small accomplishments	12.2 Set a new sugary c Party
			12.3 Celebrate the clean river!

Building Routine: “Find out where you drink sugary drinks the most, such as going out to eat, and find a healthier choice instead.”
Feeling Good: “Infuse fruits like cucumbers, berries and citrus into your water by placing sliced pieces into a water container overnight. “
Healthy Bodies: “Instead of getting your energy from sugary drinks, get them from a healthy diet of fruits, vegetables, and whole grains.”

Staying Hydrated: "Use the money you save from drinking water instead of sugary drinks to do things you enjoy."

Education message uniform for all participants:
"Ultimately, YOU can help prevent diseases associated with sugary drinks. The choices you make today have profound benefits in the future."

INSERT INFOGRAPHIC

Roswell Park Protocol Number: I 810620

Appendix J. Food Amounts Booklet

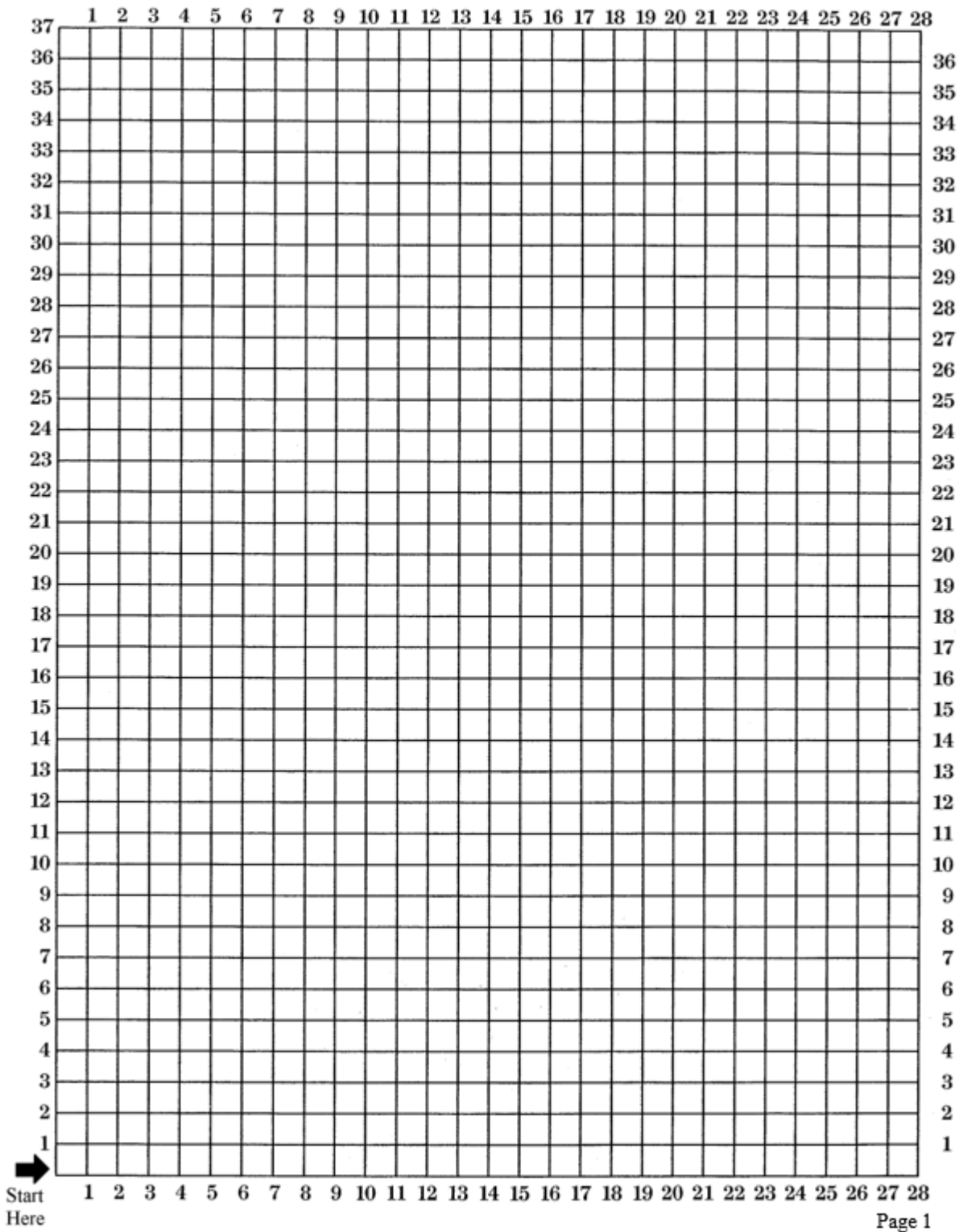
Food Amounts Booklet

Roswell Park Protocol Number: I 810620

**You will use this booklet
during the phone interview.**

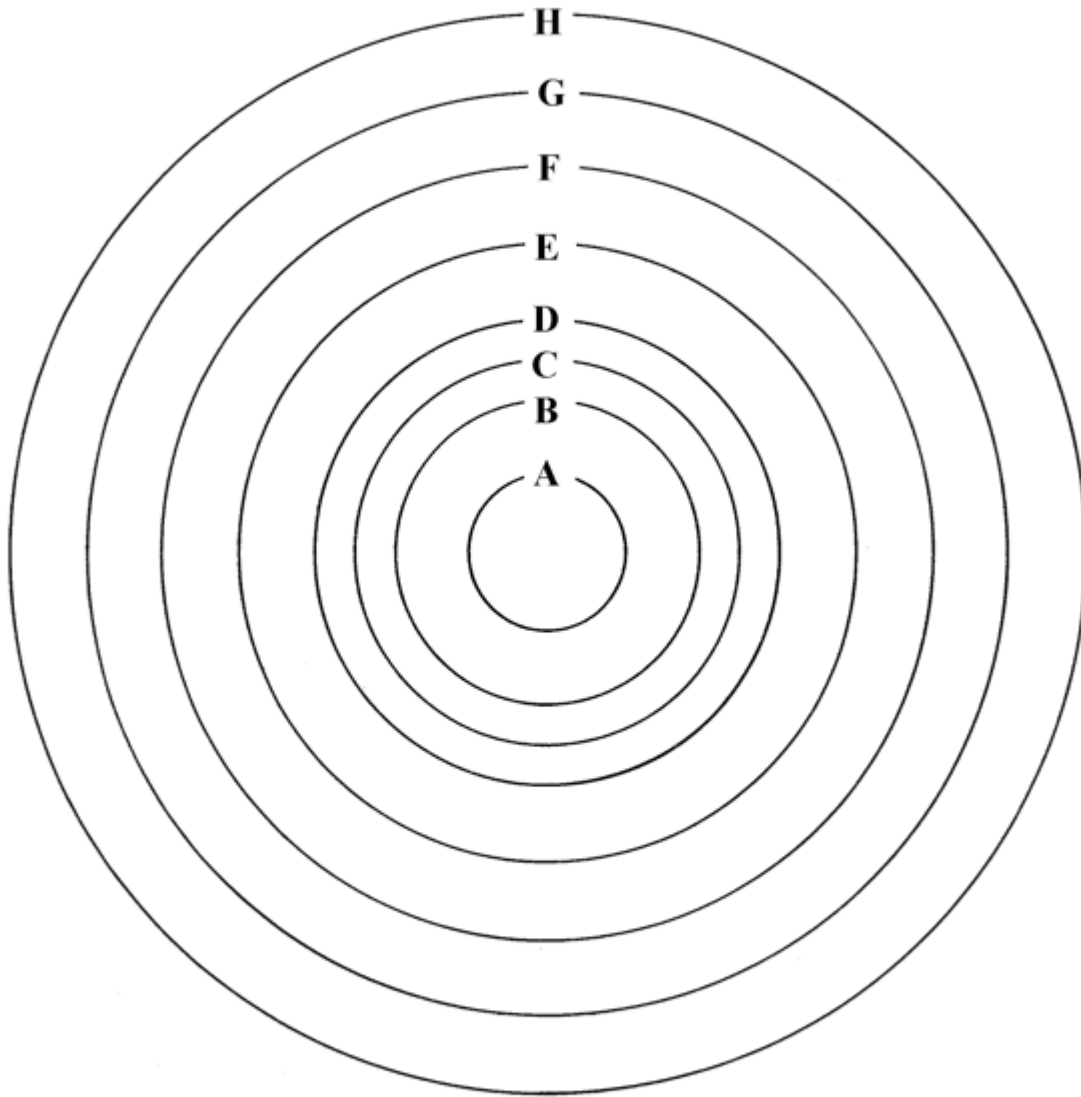
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Squares and Rectangles



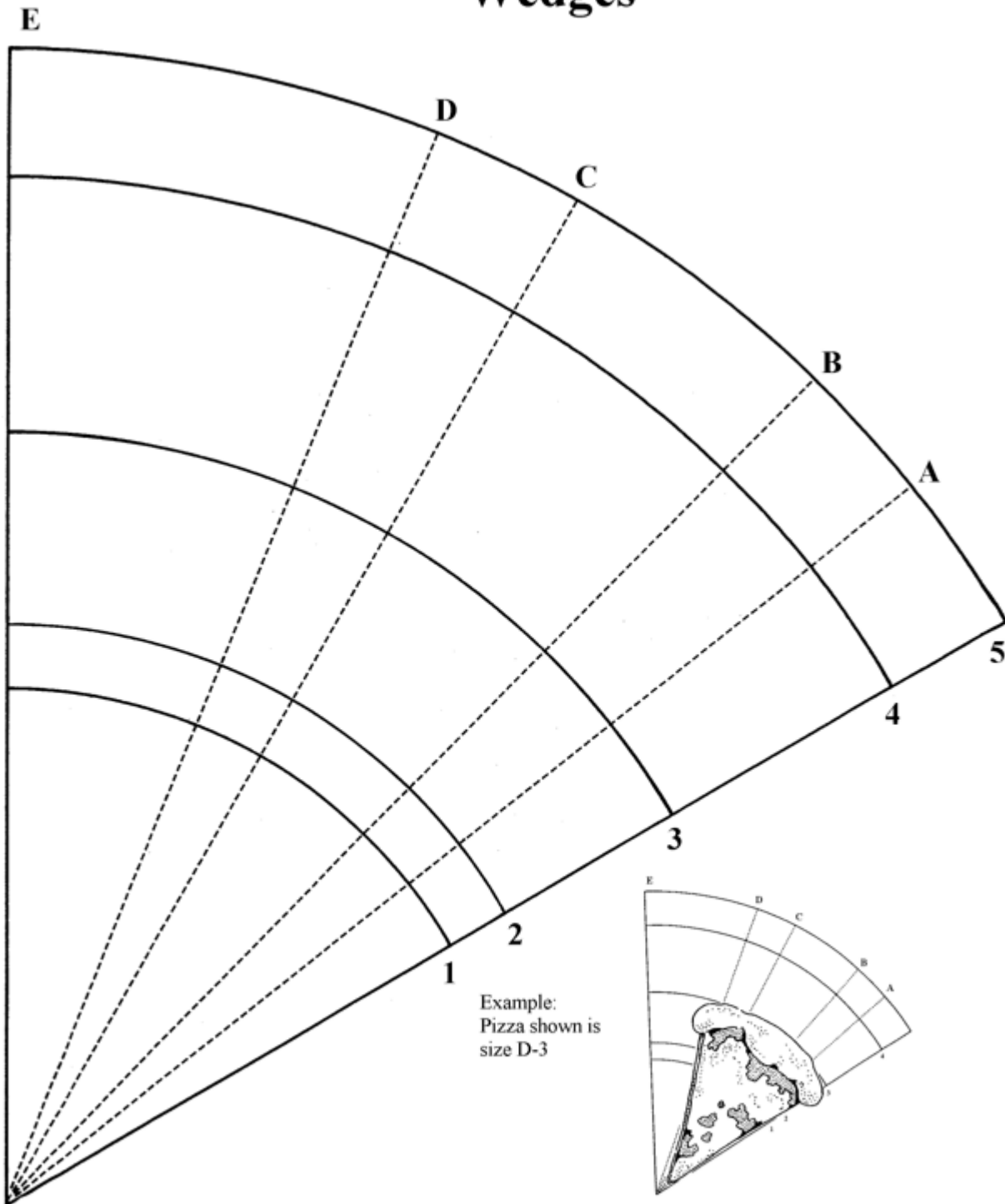
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Circles



Roswell Park Protocol Number: I 810620

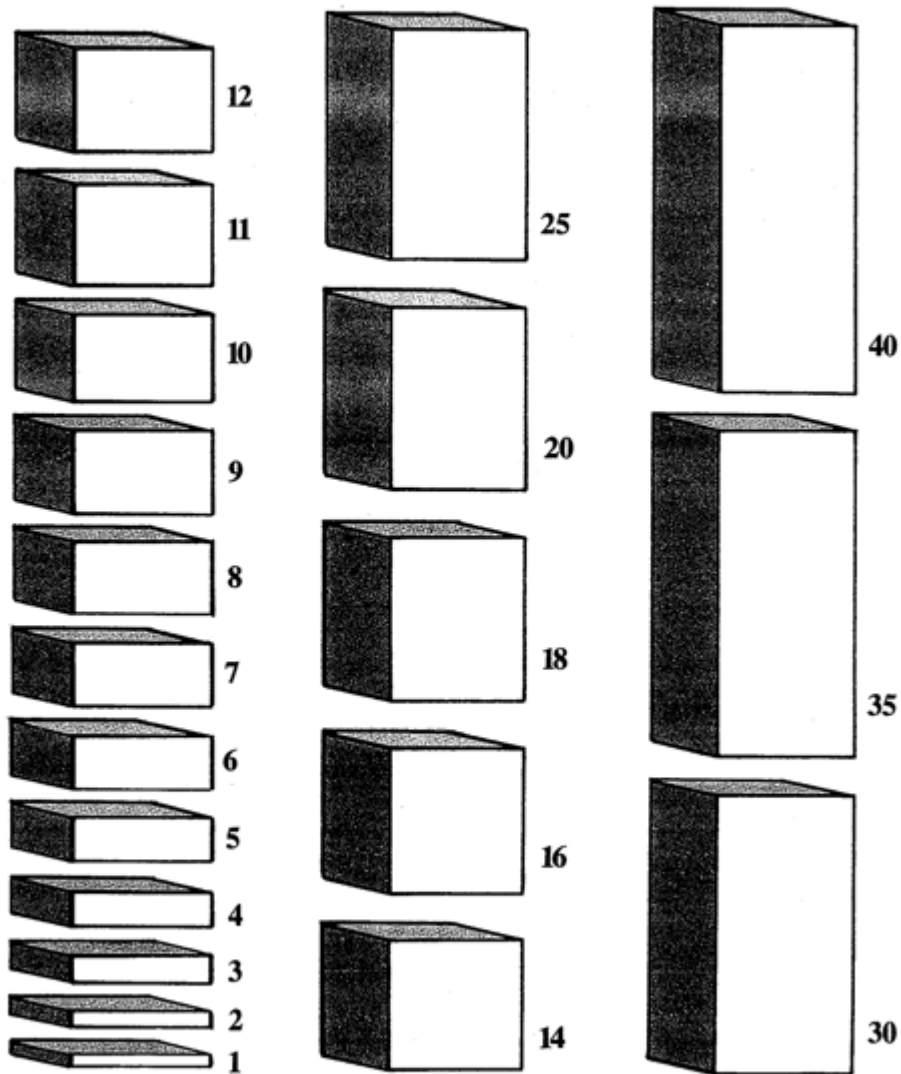
Wedges



Page 3

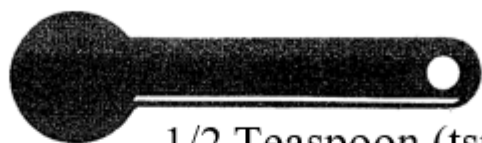
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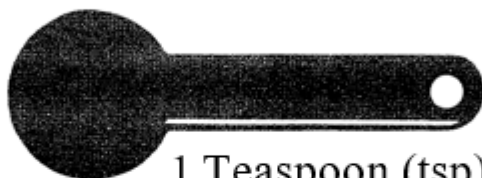


Roswell Park Protocol Number: I 810620

Measuring Spoons



1/2 Teaspoon (tsp)



1 Teaspoon (tsp)



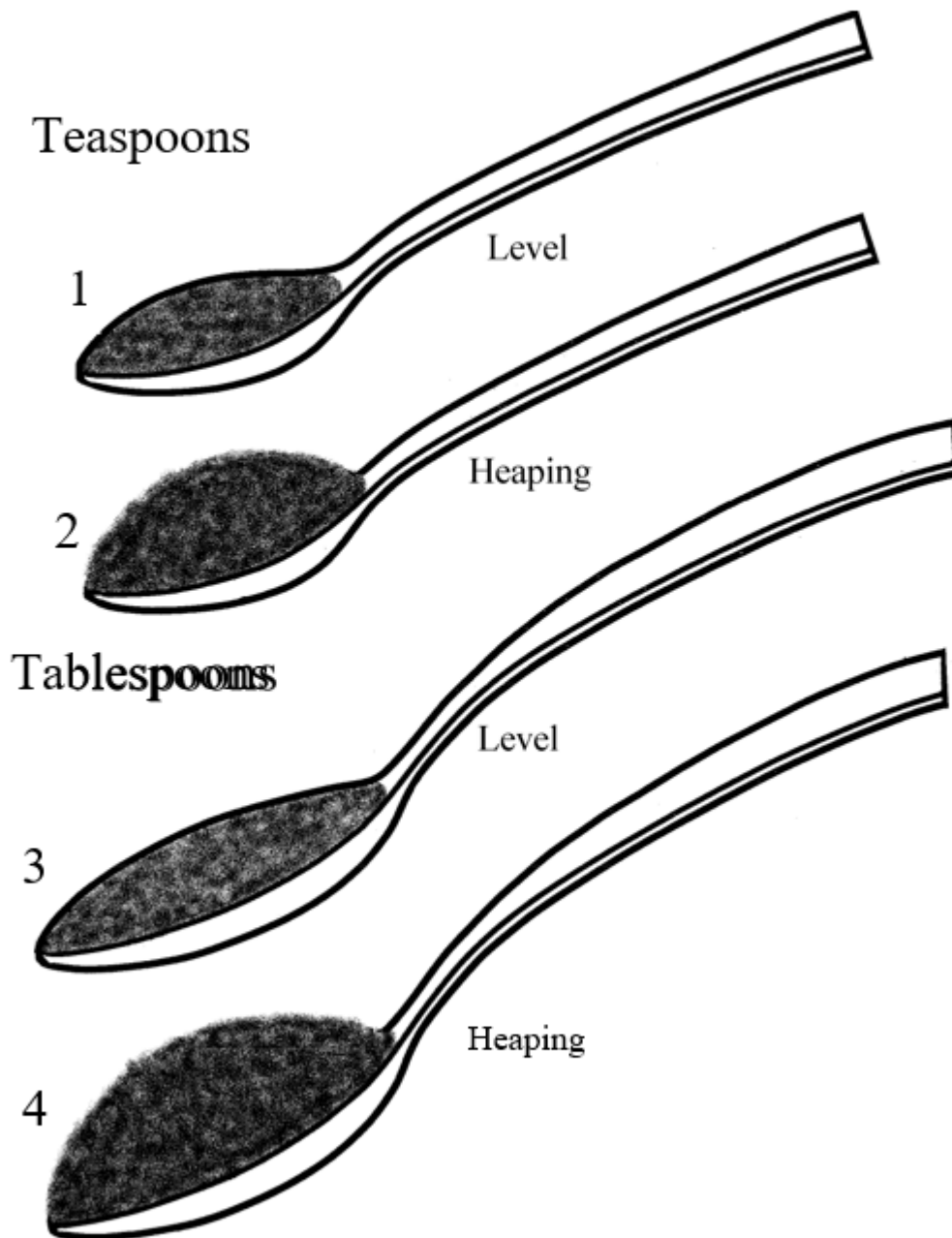
1/2 Tablespoon (Tbsp)



1 Tablespoon (Tbsp)

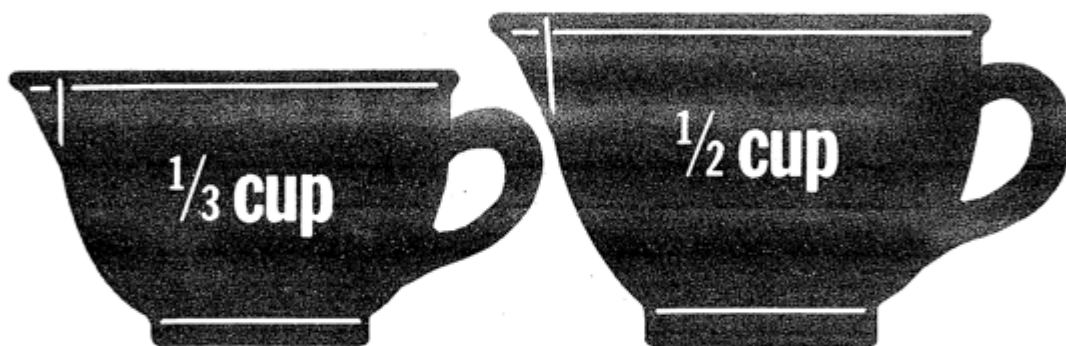
Roswell Park Protocol Number: I 810620

Eating and Serving Spoons



Roswell Park Protocol Number: I 810620

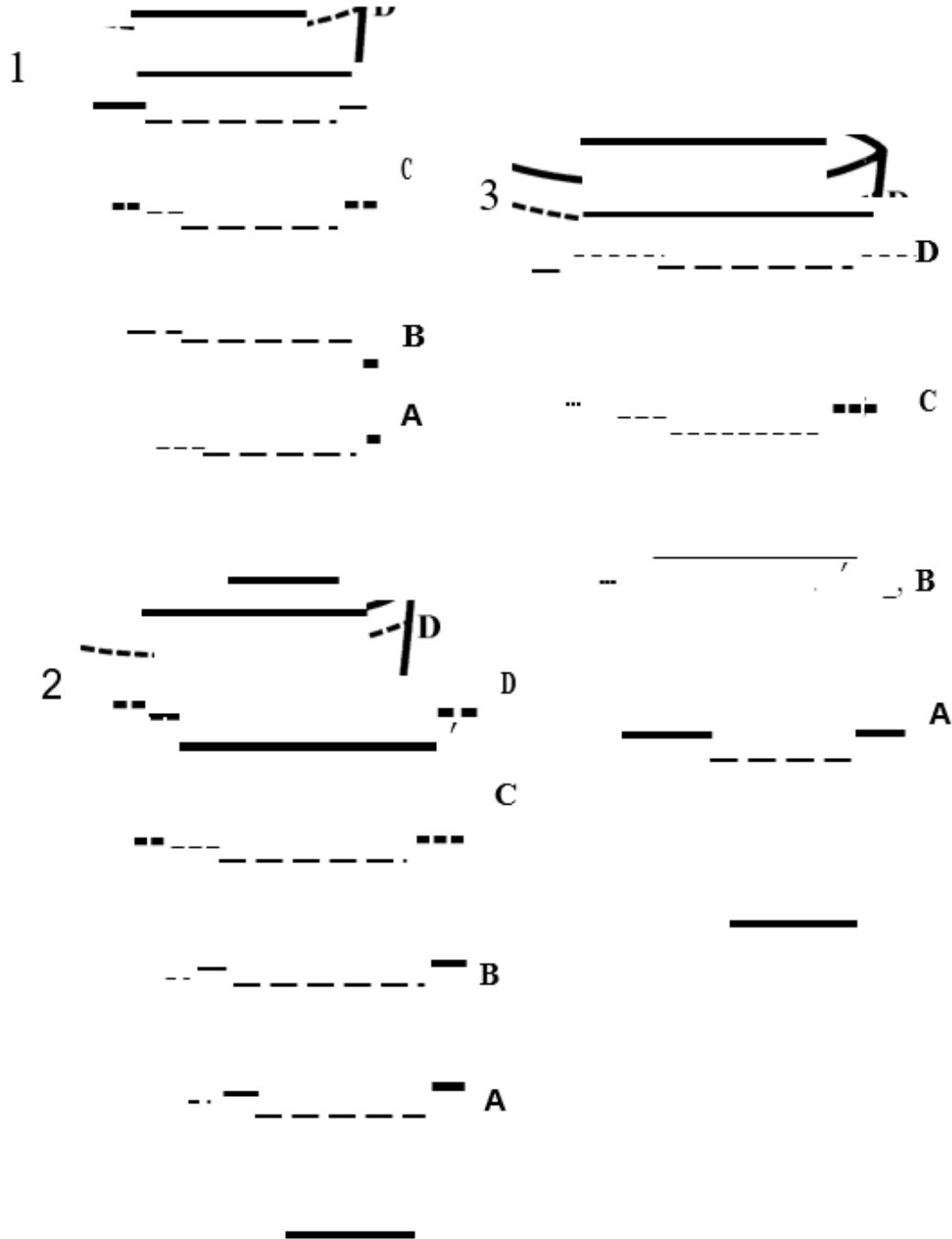
Measuring Cups



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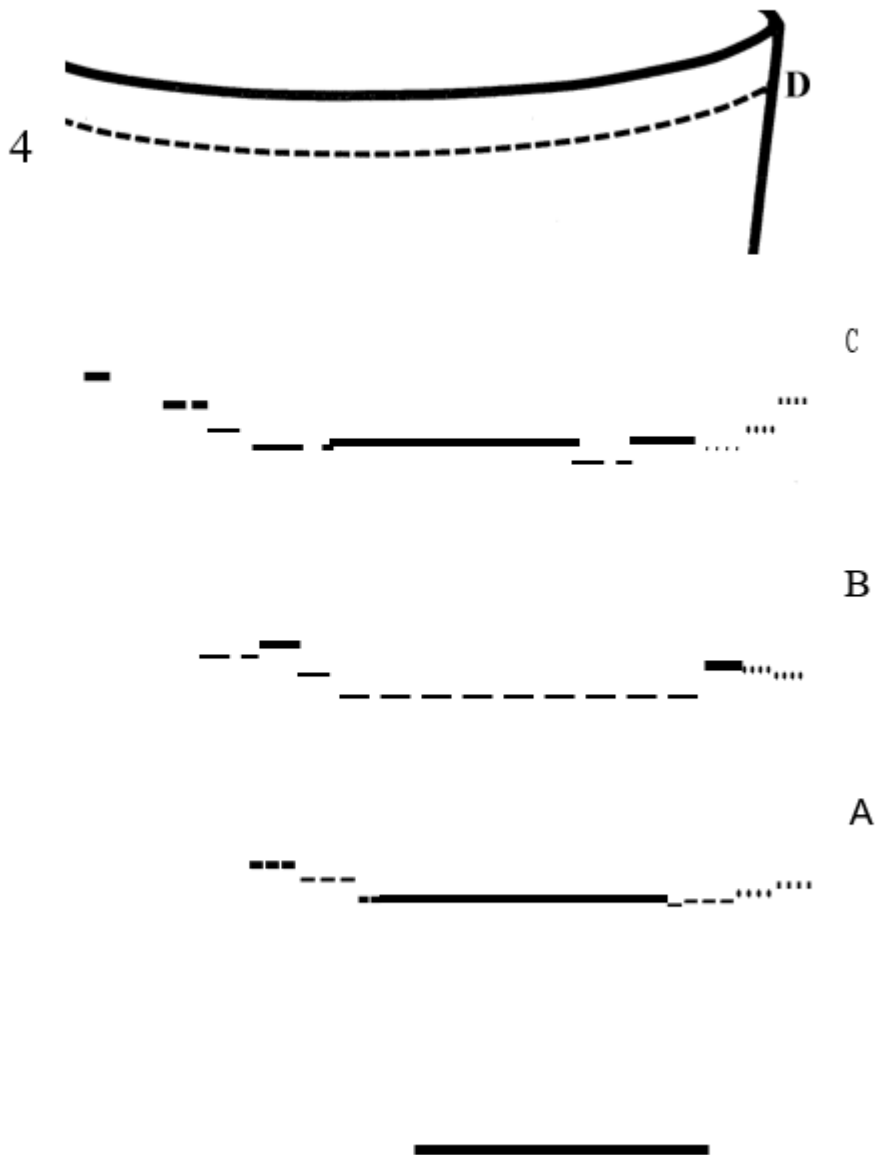
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Glasses



Roswell Park Protocol Number: I 810620

Glasses

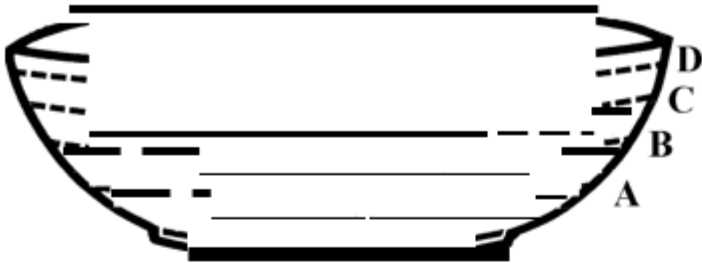


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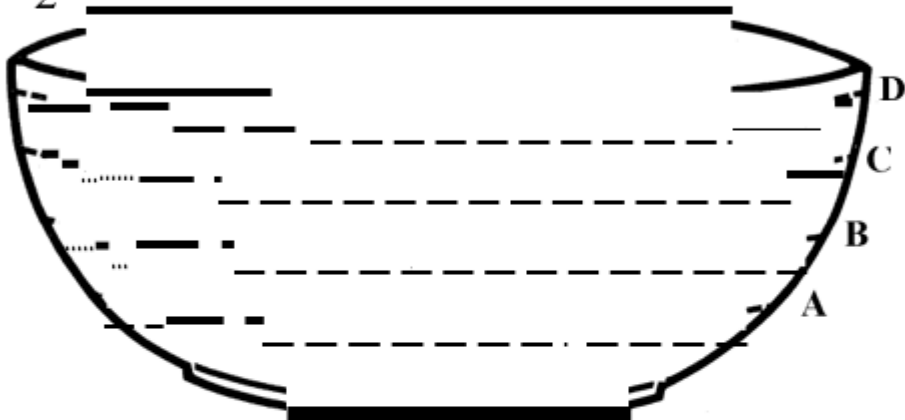
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BOWLS

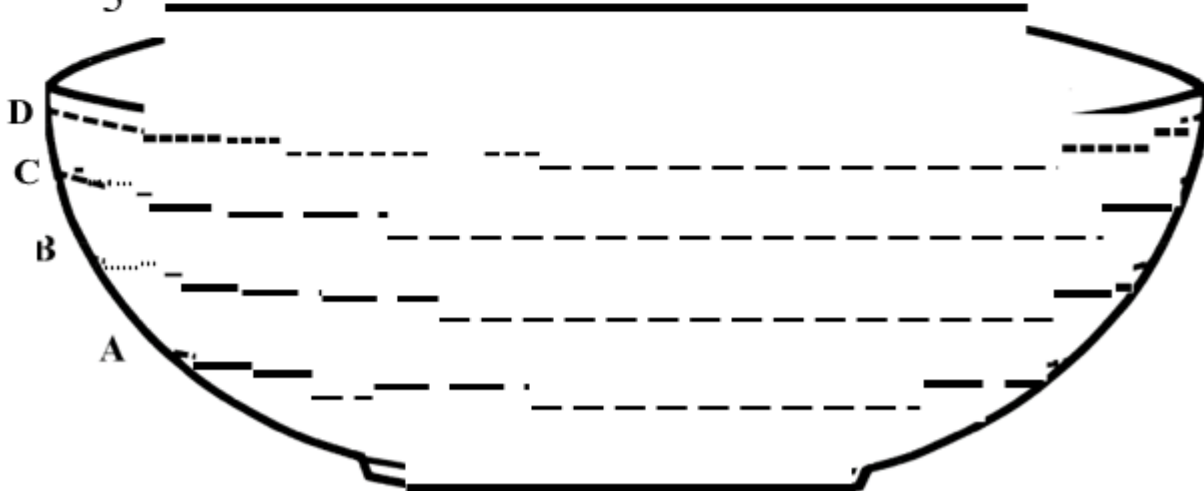
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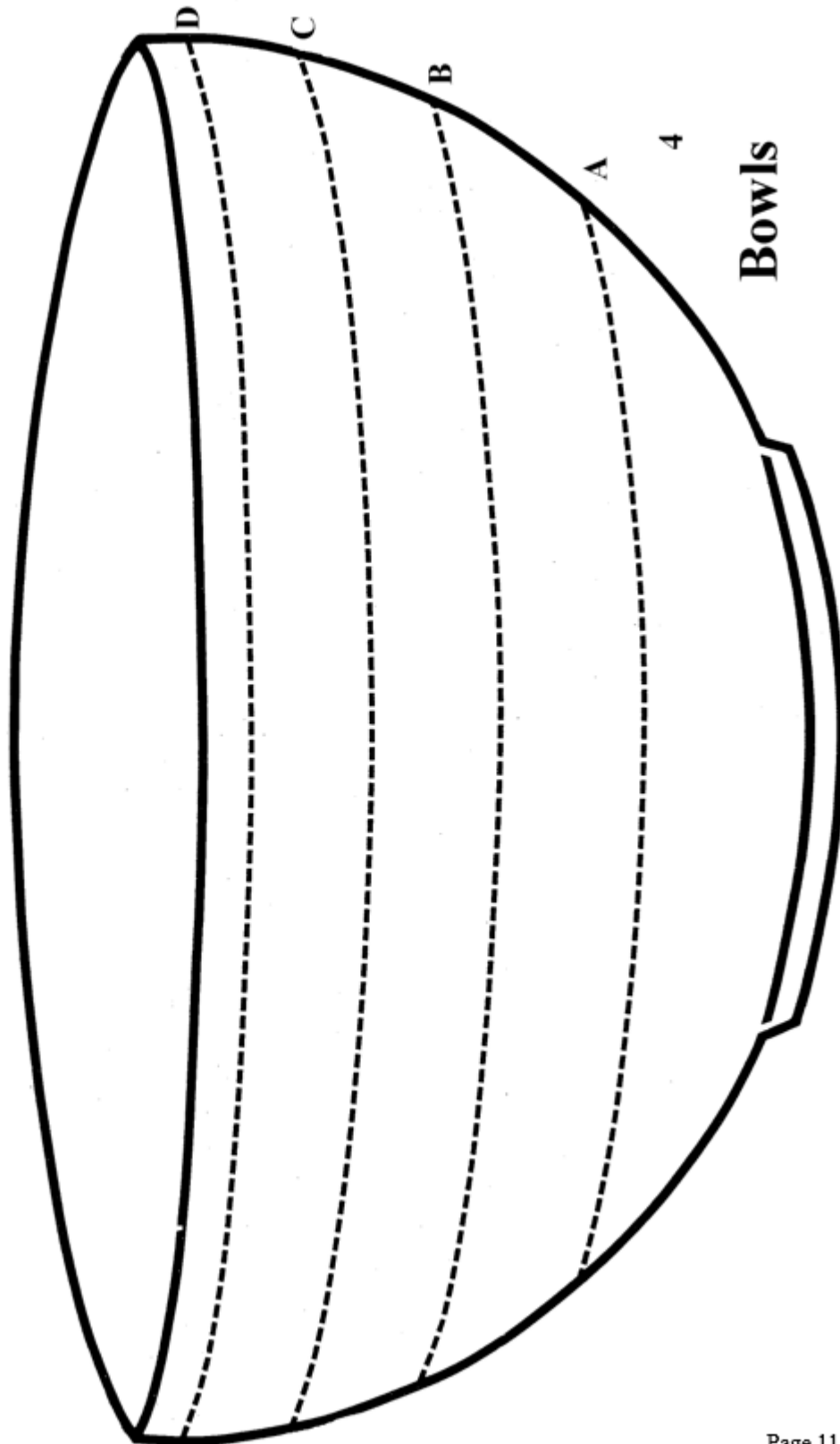
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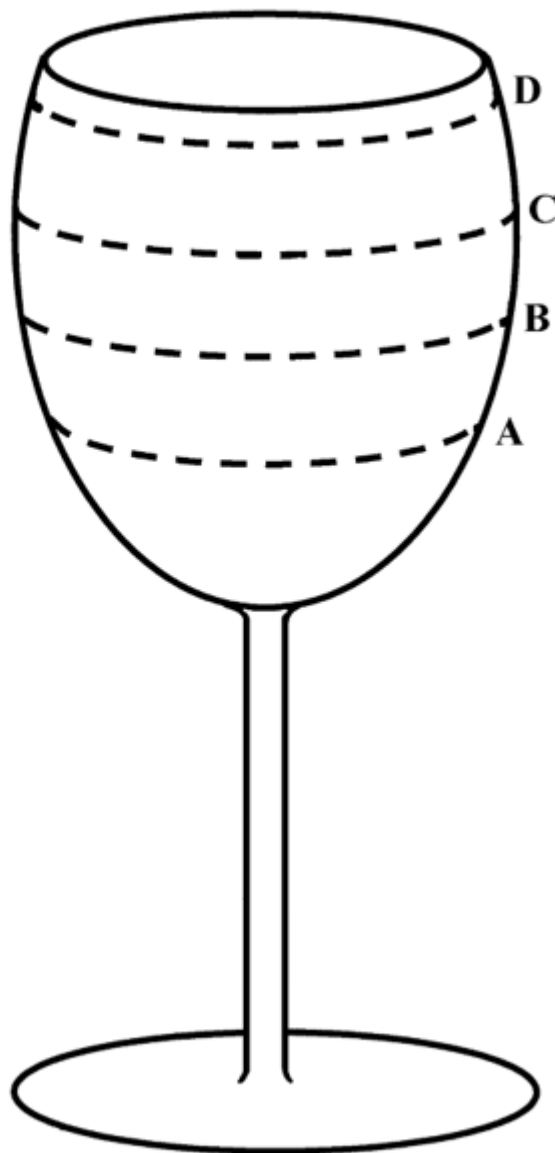
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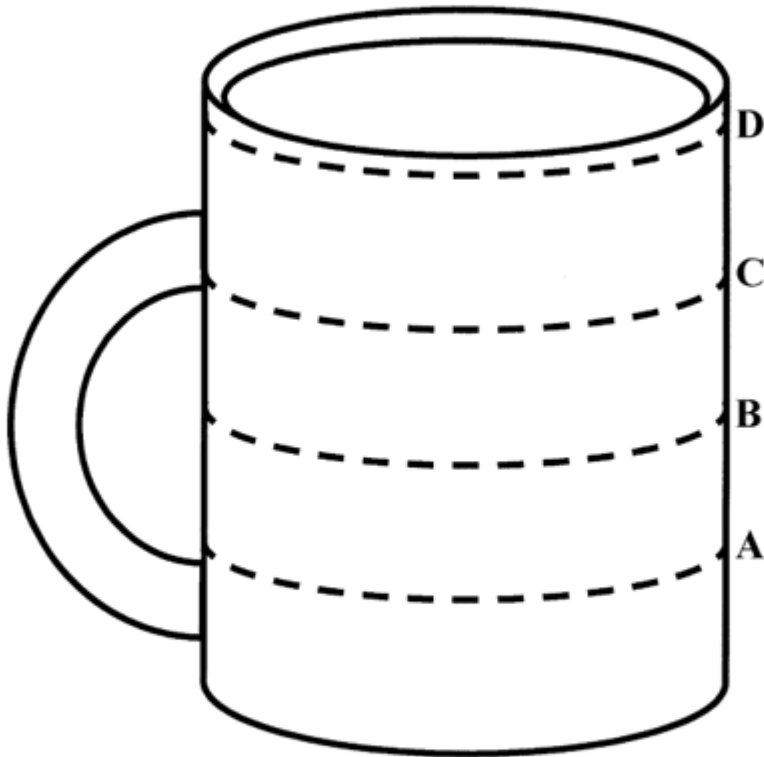
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Wine Glass



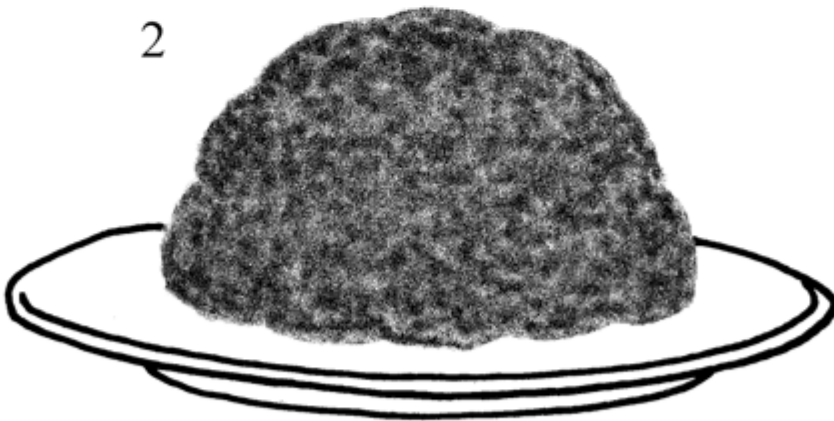
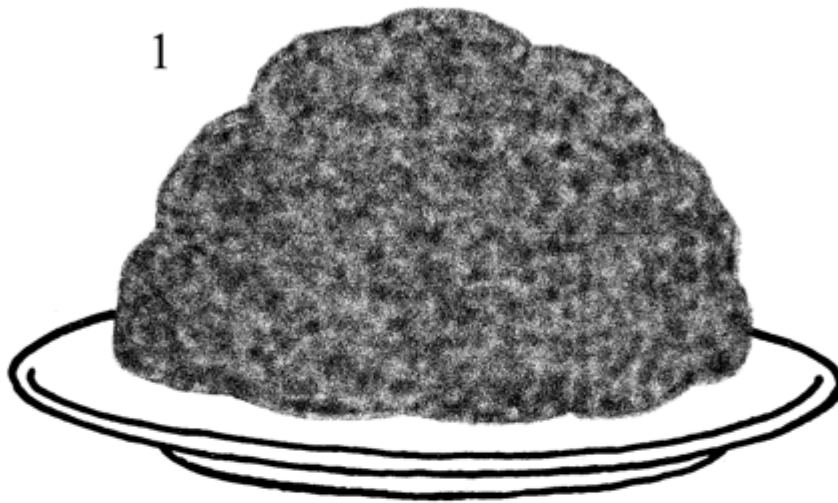
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Mug



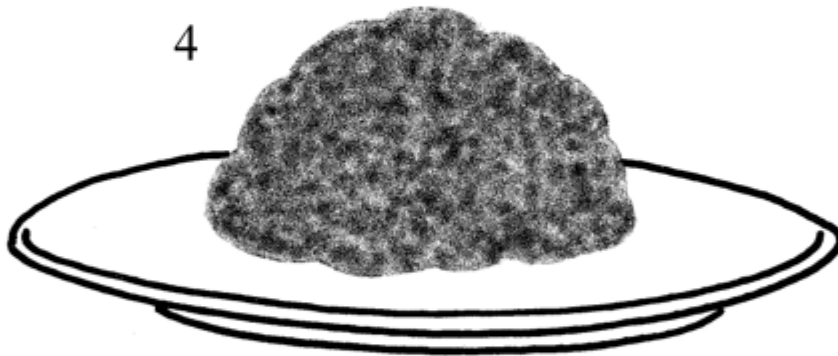
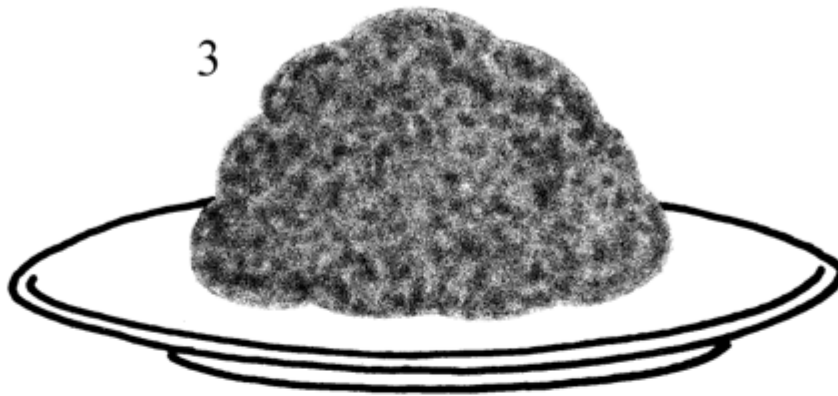
Roswell Park Protocol Number: I 810620

Mounds



Roswell Park Protocol Number: I 810620

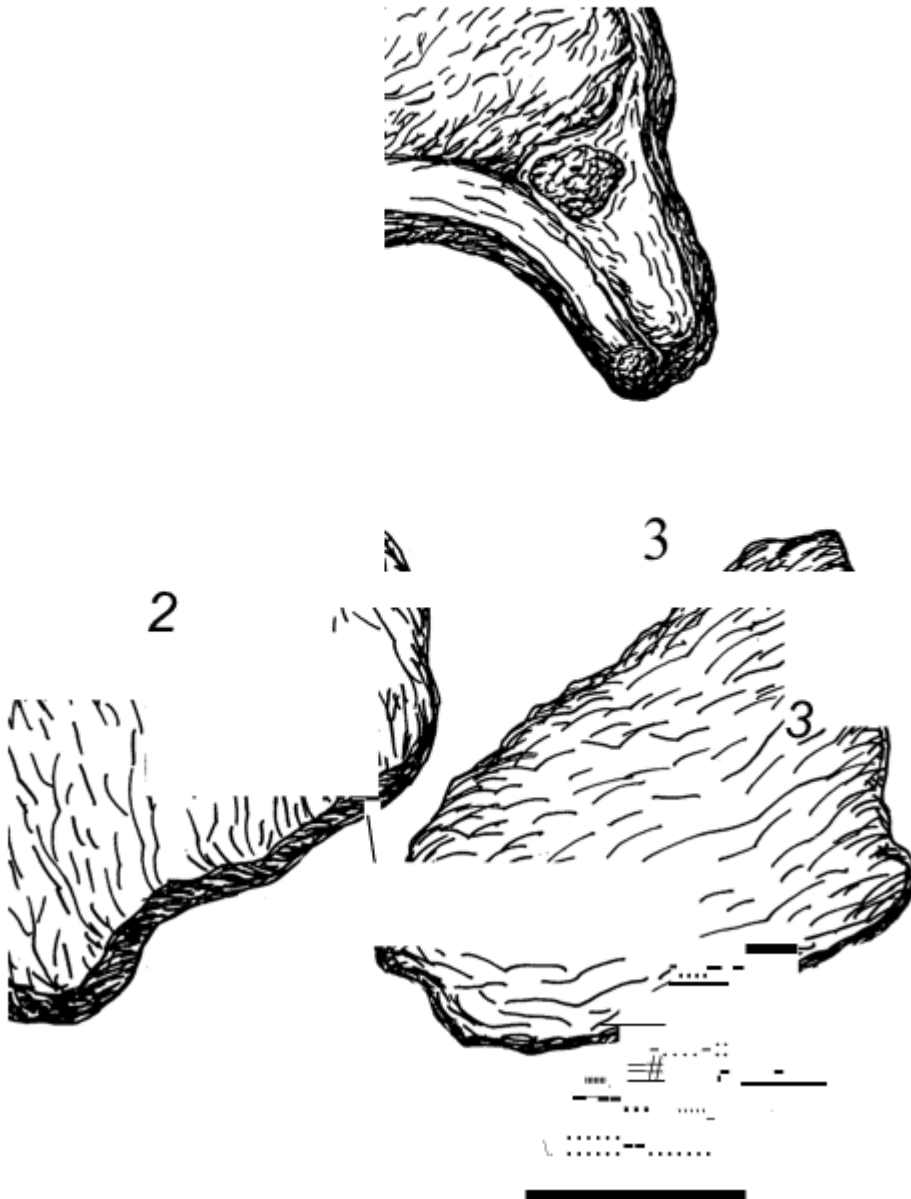
Mounds



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Meats

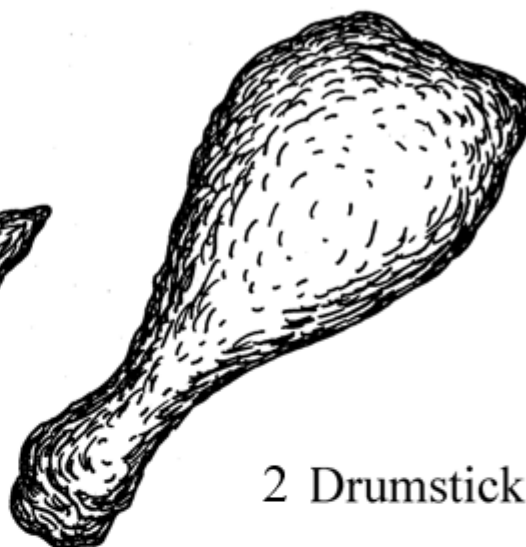


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Chicken



1 Wing



2 Drumstick



3 Thigh



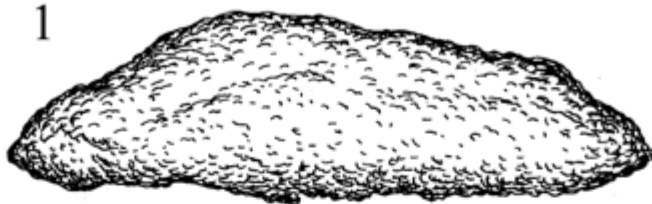
4 Breast

Page 17

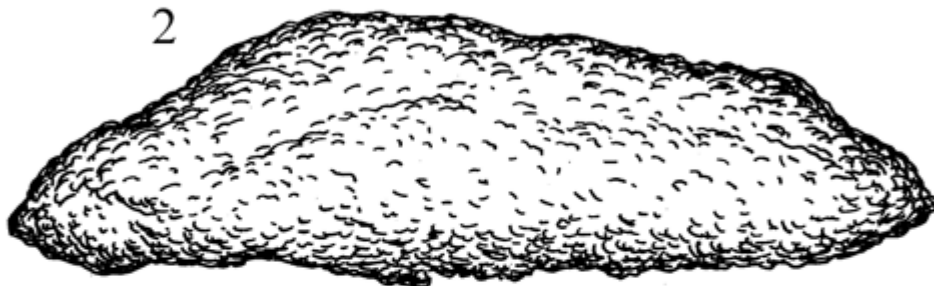
Roswell Park Protocol Number: I 810620

Fish

1



2



3



4



Roswell Park Protocol Number: I 810620

Adapted from: Van Horn LV, Stumbo P, Moag-Stahlberg A, Obarzanek E, Hartmuller VW, Farris RP, Kimm SY, Frederick M, Snetselaar L, Liu K. The Dietary Intervention Study in Children (DISC): dietary assessment methods for 8- to 10-year-olds. J Am Diet Assoc. 1993 Dec;93(12):1396-403.
Modified by Alejandra Valencia, Mary Stevens, Nutrition Coordinating Center, University of Minnesota for the Hispanic Community Health Study, Study of Latinos, 2007.