THE UNIVERSITY OF NORTH DAKOTA
CONSENT TO PARTICIPATE IN RESEARCH

Project Title: Historical trauma and resilience as a biological state and its association with the effects of the traditional Indigenous food chokeberry.

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What should I know about this research?
- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Who can join this study?
You may be eligible to join if you are an American Indian between the ages of 18-65 years and have not been consuming chokeberry products in the last six months.

You cannot join this study if you:
- Are younger than 18 or over 65 years old
- Have an allergy to chokeberry (*Aronia melanocarpa*)
- Are pregnant, lactating, or planning to become pregnant
- Have had stomach or upper gastric resection
- Are on biologic, chemotherapy or immune suppressant medications
- Are on blood thinning medications or insulin
- Have in the last two months started any new medications that lowers your blood sugar, your cholesterol, or started any anti-depressant, anti-anxiety or anti-psychotic medications in the last two months.
- Have had an acute infection in the last month or have received a vaccine in the last two months. You are still eligible for this study but will be asked to delay your participation to avoid any interactions with the study.

How long will I be in this research?
We expect that your taking part in this research will last 7 to 12 weeks depending on scheduling. It involves a pre-study visit that will last around 1 hour. You will then have a baseline

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assessment visit which will take 1.5 hours. You will then be required to pick up your chokeberry juice and drop off your empty bottles. At the end of the 6 weeks of regular chokeberry consumption you will have a final lab visit that will take approximately 15 minutes, and then a final study visit that will take approximately 30 minutes.

Why is this research being done?
The purpose of this research is to better understand the health effects of Indigenous traditional foods for Indigenous people. Going back to eating traditional foods may be beneficial to Indigenous adults. The purpose of this study is to test if consumption of chokeberry juice alters health markers of:

- metabolic endpoints such as blood cholesterol, sugar, antioxidant, and inflammation levels and urine antioxidant levels
- blood pressure
- mental health and resilience
- changes to the expression of genes in the body

What happens to me if I agree to take part in this research?
If you decide to take part in this research study, you will fill out baseline survey questions to get a better idea of your current and past health, provide a blood sample and first morning urine sample so we have measures of your health markers prior to consuming the chokeberry juice. Here is an overview of the tests and questionnaires that will be used as a part of this research:

Assessments and Tools	**Description of the blood draws and the questionnaires for this research**
Health history form with screening questions	E.g. Smoking status, activity levels, medications and supplements taken, age, 24-hour diet screen, general health history.
Interleukin 6, C-reactive protein	Markers of inflammation in your body
Other chemistry	Glucose (blood sugar) and lipids (cholesterol panel and triglycerides)
Epigenetic screen	A screen that measures activity of the genes that control inflammation.
General measures	Height, weight, blood pressure
Questionnaires	These will contain questions about your current food intake, adverse childhood experiences (ACEs), losses in your life (examples- loss of language, culture etc.), resilience, and level of anxiety and depression.

You will then go home with the chokeberry juice where you will consume 100ml of the water-infused juice twice per day. You will be able to dilute the juice with water to your taste. You will

be provided a tablespoon to take home with you to measure the juice extract to mix with water as instructed. You will eat your usual diet. You will bring back your empty bottles of chokeberry juice at the completion of the 6 weeks of consuming the juice. You may receive daily text message reminders to help you remember to consume the chokeberry juice twice daily. After the six weeks of drinking the juice, you will come into the Altru blood draw site one more time for blood work, provide a first morning urine sample. To complete your participation in the research, you will fill out a final set of survey questions. This table will summarize your participation steps:

Study Visits	**Summary of your visits:**
Introduction Visit	Review of study, consent form review and signing, tax form completion, given urine collection cup to take home as well as instruction for the 12 hours fast before the first blood draw. This visit will last about 30 minutes.
1st Visit	Morning blood draw appointment (15 milliliters of blood will be drawn (about a tablespoon)) after 12 hours of fasting (water is ok), bring in first morning urine sample, fill out baseline questionnaires. This visit will last about 1.5 hours.
Chokeberry consumption	You will consume the chokeberry juice for a period of 6 weeks. You will bring back your empty bottles of chokeberry juice at the end of the study. You may receive daily text message reminders to help you remember to consume the chokeberry juice twice daily.
2nd Visit	Once you have completed six weeks of taking the chokeberry juice, you will fast for 12 hours (water is ok) and come into the lab first thing in the morning with an already collected urine sample. At the lab your blood will be drawn a final time ((15 milliliters of blood will be drawn (about a tablespoon)). The research assistants will meet you to fill out the final questionnaires and this will complete your participation in the research. This visit will last about 45 minutes.

We have compiled an addendum to this consent form with a more detailed description of what will happen in each of your visit for easy viewing. The addendum is titled: *Chokeberry Study Addendum- Study Steps in Detail*.

Could being in this research hurt me?
The most important risks or discomforts that may be possible from taking part in this research include:

Blood draws: The risks if blood draws are small and as a rule are limited to local bruising or swelling. Problems may include slight pain and dizziness. You may feel faint or may faint during or right after a blood draw. This causes no long-term harm. Relief is achieved by putting your head down between your knees or by lying down. If you have had problems with fainting during blood draws in the past, you may be more likely to have them again. A bruise may result at the

draw site. Later problems might include a blood clot or infection. However, these worries are very rare. At the 1st and at the 2nd blood draws, 15 milliliters of blood (about a tablespoon) will be drawn. A total of 30 milliliters of blood (a little over 2 tablespoons) will be drawn over the 7 weeks. This is well within safe levels. For example, the blood bank donation limit is 475 milliliters (1 pint) every 8 weeks. The blood will be drawn by personnel trained in drawing blood.

Urine sample: There are no obvious safety risks for collecting a urine sample at home. A participant could feel self-conscious in needing to collect their own urine and bring it into the lab for assessment. Privacy will be maintained during the drop offs of urine samples to the laboratory.

Questionnaires: There are no risks in participating in this portion of the research beyond those experienced in everyday life. For some individuals, questions on adverse childhood experiences or historical loss can trigger certain emotions. If you experience emotional stress as a result of participating in this study please call the National Alliance on Mental Illness (NAMI) mental health support line at: 1-800-950-NAMI or text "NAMI" to 741741.

Chokeberry juice: Chokeberry juice is a commercially available juice extract available widely in the US (Superberries-Aronia Juice Concentrate). There have been several human studies to date demonstrating safety with this food item. With any food agent there is always a risk of having an allergic reaction or developing one after initial consumption. Chokeberry has been identified to potentially lower blood sugar levels which may be a beneficial response; however, if you are a type 2 diabetic, you may need to ensure careful monitoring of your blood sugar levels to see if adjustments are needed to keep your blood sugars levels in a healthy range (Type 1 diabetics or Type 2 diabetics on insulin are not able to participate in this study).

Will being in this research benefit me?

- The data collected in this study may help others in the future.
- You may have temporary physical benefits including reduction of cholesterol, blood sugar, and blood pressure depending on the efficacy of the chokeberry juice used in this study.
- You might reconnect with a traditional and culturally significant American Indian food product.
- You may also not benefit from participation in the study.

How many people will participate in this research?

About 50 people will take part in this study based at the University of North Dakota and partnered with the USDA Grand Forks Human Nutrition Research Center and Altru Health System.

Date: _____

Subject Initials: _____

Will it cost me money to take part in this research?
You will be expected to provide your own transportation to and from the Altru lab draw site. We do not withhold income, social security, unemployment taxes, or any other taxes because you are not an employee of UND or the USDA Human Nutrition Research Center. You may have to pay income taxes on the money you received. All tax questions relating to the taxability of the payment should be directed to your personal tax accountant or to your local Internal Revenue Service Office. If you are not a United States citizen, check your documentation to make sure you can receive money without risking your status in the United States.

Will I be paid for taking part in this research?
You will be paid for being in this research study. You will receive $285 if you complete all requirements for the study. If you choose not to continue in the study or are found to no longer qualify, you will receive payment pro-rated for the portions of the study you did complete as shown below:

Screening Visit: $10 per 30-minute interval for a max of $40/visit will be given.
Blood draw: $15 each visit blood is collected
Finger Stick blood draw: $5
Urine collection: $10 per collection
Food diary collection: $20
Questionnaires: $10 each visit completed
Bonus for completing all steps of the research process: $85

Who is funding this research?
The National Institutes of Health (NIH) is funding this research study.

What happens to information collected for this research?
Your private information may be shared with individuals and organizations that conduct or watch over this research, including:
- The research sponsor: The National Institutes of Health
- The Institutional Review Board (IRB) that reviewed this research
- Office of Research Compliance & Ethics

We may publish the results of this research. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law. You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court or to tell authorities if we believe you pose a danger to yourself or someone else.

Confidentiality will be maintained by means of assigning study participants unique subject identification (ID) numbers that will not contain any personal identifiers. This subject ID number will be used on all data collection instruments, including questionnaires and computer records, so

that no data can be connected to an individual subject. A master list linking the participants' names to the ID numbers will be kept in separate locked files at UND and at the USDA Grand Forks Human Nutrition Research Center, or in a computer file with a password protected access restricted to study personnel. If any of your blood tests or screens report a concerning health finding, this master list will be used to notify you and set you up with a referral to your healthcare provider to address the concern. Clinical trial information will be submitted to the National Institutes of Health/National Library of Medicine to be included in the clinical trial registry data bank (www.clinicaltrials.gov); however, this submission will not contain any personally identifiable information.

Data or specimens collected in this research will not be used or distributed for future research studies, even if identifiers are removed. If you would prefer to have your *blood* samples returned back to you, please make this this request here:

(*Please circle one*)
YES (I would like my blood samples returned to me and I acknowledge I will need to pick up what remains of the samples from the USDA Human Nutrition Research Center)
NO (I do not want my blood samples returned and I acknowledge they will be disposed of once the needs of this research study are completed)

Could being in this research hurt me?
In the event that this research activity results in an injury, treatment will be available including first aid, emergency treatment and follow-up care as needed. Payment for any such treatment is to be provided by you (you will be billed) or your third-party payer, if any (such as health insurance, Medicare, etc.) No funds have been set aside to compensate you in the event of injury by UND, the USDA, or Altru. Also, the study staff cannot be responsible if you knowingly and willingly disregard the directions they give you.

What if I agree to be in the research and then change my mind?
Yes, you may choose not to join or you may stop taking part at any time in the study without penalty or loss of benefits to which you are otherwise allowed. Your decision will not affect your current or future relations with UND, the USDA Human Nutrition Research Center, or Altru Health System. If you decide not to do any more of the research tests, we ask that you notify the study coordinator or principal investigator.

You will be informed by the research investigators of this study of any significant new findings that develop during the study which may influence your willingness to continue to participate in the study.

There may be certain medical circumstances where you may be removed from the study without your prior approval. If there is deteriorating health or other conditions that might make continued participation harmful to you, we will ensure your safety is put first.

Date: _____
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Who can answer my questions about this research?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 701.777.4279 or UND.irb@UND.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.
- You may also visit the UND IRB website for more information about being a research subject: http://und.edu/research/resources/human-subjects/research-participants.html

Your signature documents your consent to take part in this study. You will receive a copy of this form.

Subject's Name: _____

_____ _____
Signature of Subject Date

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative.

_____ _____
Signature of Person Who Obtained Consent Date

Approval Date: 3/31/2022

Expiration Date: 10/14/2022

University of North Dakota IRB

Date: _____
Subject Initials: _____