CONSENT TO BE PART OF A RESEARCH STUDY

THINKING ZINC

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and discusses the risks and possible benefits to you if you choose to participate in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers or study liaisons about the study and ask them any questions you have. You may also wish to talk to others (friends, family members, or your doctor) about your participation in this study. If you decide to take part in this study, you will be asked to sign this consent form. Before you sign the form, be sure you understand what the study is about, what you will be asked to do, and any possible risks and benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study Title: "Thinking Zinc"

1.2 Agency sponsoring the Study: This study is funded by the National Institute of Environmental Health Sciences (NIEHS) Superfund Research through a grant to the University of New Mexico (Grant number - 5P42ES025589).

1.3 Names, degrees and affiliations of researchers conducting the Study: This study is led by Drs. Laurie Hudson, PhD., Debra MacKenzie, PhD., and Esther Erdei, PhD., MPH, from the University of New Mexico (UNM) Health Sciences Center, College of Pharmacy, Department of Pharmaceutical Sciences and members of Community Environmental Health Program (CEHP) and Christopher Shuey, MPH, with Southwest Research and Information Center (SRIC).

2. PURPOSE OF THE STUDY

2.1 Study Purpose: Metals are commonly found in abandoned uranium mine and milling waste sites that are prevalent on Navajo Nation. These metals can get into your body through food, water or dust. Studies have shown that metals such as uranium, arsenic and mercury can damage cells in your body and there is some information to show that this damage can be decreased when sufficient zinc is present. This study will ask whether taking daily zinc pills at the USDA recommended dose will protect the body's cells from the effects of exposure to metal contaminants.

3. INFORMATION ABOUT STUDY PARTICIPANTS

Taking part in this study is completely **voluntary.** You do not have to participate if you don't want to. You may also leave the study at any time. There will be no penalty to you if you leave the study before it is finished.

3.1 Who can take part in this study?

You may participate in this study IF:

1) You are between the ages of 21 and 64.

2) You live in or near the participating communities of Blue Gap Tachee Chapter (Az) and Red Water Pond Road Community (NM).

3) You are willing to attend four (4) study visits at a local site on scheduled dates, over a 9 month period.

4) You are willing to provide blood and urine samples at each study visit.

5) You are willing to take daily zinc pills at a dose equal to the USDA recommended daily dietary amount.

You CANNOT participate in this study IF:

1) You are pregnant or nursing or planning to become pregnant during the course of the study.

2) You are diabetic.

3) You are currently taking and/or plan to take multivitamins containing zinc.

4) You have a known or suspected allergy to zinc.

5) You have ever been diagnosed with syndromes of copper imbalance.

3.2 How many people are expected to take part in this study?

We will enroll one hundred (100) people to participate in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you agree to participate in this study the following things will happen:

We will ask you to participate in **4 scheduled visits over the course of this study**. These visits will occur at a local chapter house or other convenient community location.

On the first scheduled visit:

- You will fill out a questionnaire that will help us to better understand the results of our study.
- You will provide a small amount of blood (1 tablespoon) and urine (3 tablespoons).
- You will receive a $30 merchandise card to compensate you for your participation at this visit.

On the second scheduled visit (approximately 3 months later):

- We will ask you a few questions to make sure you are still able to continue to be in the study.

- You will fill out a survey that asks about the food you eat which will help us to better understand the results of our study.
- You will provide a small amount of blood (1 tablespoon) and urine (3 tablespoons).
- You will receive a 3 month supply of zinc pills to take once a day at a dose equal to the USDA recommended daily amount.
- You will receive a $30 merchandise card to thank you for your participation at this visit.

On the third scheduled visit (approximately 3 -6 months later):

- We will ask you a few questions to make sure you are still able to continue to be in the study.
- You will provide a small amount of blood (1 tablespoon) and urine (3 tablespoons).
- You will bring any unused pills with you to the visit so that researchers can count how many pills you might have missed.
- You will receive a 3 month supply of zinc pills to take once a day at a dose equal to the USDA recommended daily amount.
- You will receive a $30 merchandise card to thank you for your participation at this visit.

On the fourth and final scheduled visit (approximately 3 months to 6 months later):

- You will fill out a survey that asks about the food you eat which will help us to better understand the results of our study.
- You will provide a small amount of blood (1 tablespoon) and urine (3 tablespoons).
- You will bring any unused pills with you to the visit so that researchers can count how many pills you might have missed.
- You will receive a $60 merchandise card to thank you for completing all 4 study visits.

During the course of the study, community liaisons will contact you to ask how you are feeling and to find out if you have any questions or concerns related to your participation in the study. They will also notify you of upcoming scheduled visits.

4.2 How much of my time will be needed to take part in this study?

Each study visit could take from 1-2 hours. The first visit will be the longest in order to explain the study and obtain consent for your participation. We will ask you to come to a local chapter house or community center on the scheduled day and time for each of the four study visits.

4.3 When will my participation in the study be over?

Your participation in the study will be complete after the 4th visit, approximately 9-15 months after the first visit.

4.4 What will my blood and urine be used for?

The researchers will use your blood and urine to look for the presence of uranium, arsenic, mercury, and zinc. They will look at cells found in your blood for evidence of cellular damage or evidence of DNA damage and

DNA repair processes. At no point will your personal DNA be collected and no genetic information will be obtained. The researchers will also look at what types of immune cells are present in your blood and measure how those cells act outside of the body in experimental conditions. They will look at all of these different measures before and after you take the zinc pills to see if there are any changes related to the presence of zinc.

5.0 INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in this study?

For part of the study, you will be given a zinc pill to take on a daily basis. Zinc is the FDA category of "generally recognized as safe". The proposed dose of elemental zinc (10 mg) is amount recommended by USDA as the daily standard amount for adults and one fourth or a quarter of the established upper daily limit (40 mg).

Some people may be sensitive to zinc and may experience some of the following symptoms: nausea, vomiting, loss of appetite and abdominal cramps which can occur in up to 10% of people taking zinc pills. These symptoms might not happen if you eat food when taking the zinc pill. If you choose to stop participating in the study and stop taking the pills these symptoms should go away.

Using zinc lozenges for a sore-throat while participating in this study is not recommended and could increase the amount of zinc you are receiving in your body. Please notify study personnel if you have used zinc lozenges while participating in this study.

A rare, but serious potential adverse response is an allergic reaction to zinc that could lead to breathing difficulties, skin rashes and/or swelling of the face, mouth, tongue or throat. **You should not take any more zinc pills if you experience any of these symptoms. You should call your regular doctor or the doctor listed in section 9.**

Zinc has been shown to improve blood sugar levels which could result in changes in the way your body responds if you are taking medicine for diabetes, therefore, individuals who are diabetic should not take part in this study.

There are minimal risks associated with giving blood. Blood samples will be drawn using the same procedures used in standard hospital testing procedures. The most common risks of having a blood sample taken are temporary discomfort or pain from the needle stick, occasional bruising, sweating, light-headiness, and in rare cases, faintness or infection.

There are no health risks associated with giving a urine sample.

You may experience stress and emotional distress when learning about environmental exposures or finding out that you have harmful metals in your body and how they may affect your health.

You may experience some inconvenience with participating in this or any research study.

While every effort will be made to maintain strict confidentiality of all of your personal identification, we cannot guarantee that all study data will always be secure and there may be a loss of privacy.

As with any research study, there may be additional risks that are unknown or unexpected. If any additional risks are identified during the course of the study you will be notified of these risks by researchers or community liaisons.

5.2 What happens if I get hurt, become sick, or have other problems related to this research?

You may experience side effects related to your participation. If you become sick or experience other problems from participation in this study, stop taking the zinc pills immediately and notify study personnel (your local liaison, the study PI's, or other contacts provided on this form in Section 9). You should also tell your regular doctors if you have concerns regarding your health.

In the event that you have an injury or illness that is caused by your participation in this study, reimbursement for all related costs of care will be sought from your insurer, managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

If you feel you have been injured or become sick because of taking part in this study you may call the Chair of the Navajo Nation Human Research Review Board (NNHRRB) Ms. Beverly Becenti-Pigman at (928) 871-6929.

5.3 If I participate in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the study. You should not take part in more than one study without the approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You might not receive direct personal benefits from being in this study.

You might benefit by taking zinc pills because your body naturally uses zinc to keep you healthy. Having enough zinc in your body is important for healthy DNA, good immune function, wound healing and for healthy growth during childhood. Having enough zinc in your body has also been shown to improve learning and memory and to potentially reduce the duration of a cold infection.

Being in the study could benefit both you and your community by learning more about exposure to harmful metals within your community through the information provided by study. Both you and others could benefit if this study finds out that zinc can protect cells in your body from damage by harmful metals.

You might benefit by learning if harmful metals are present in your body and learning how to reduce your exposure to these metals.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will inform you if they learn important new information that may change your decision to be a part of this study.

6.0. ENDING THE STUDY

6.1 If I want to stop participating in this study, what should I do?

Your participation in this study is voluntary and you are free to leave the study at any time. If you leave before the study is finished, there is no penalty to you or effect on your health. After you stop participating the researchers will not get any more information from you, however, any information from your surveys or samples obtained before you stopped participating will be included in the study results. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record.

If you decide to leave the study, please tell either the local liaison, or other contact persons listed in Section 9.

6.2 Could there be any harm to me if I decide to leave the study before it is finished?

Leaving the study before it is finished will not cause any harm to you.

6.3 Could the researchers take me out of the study before it is finished?

Yes. There are several reasons why the researchers may need to end your participation in this study. Some examples are:

- You become ineligible to participate.
- You do not wish to take the zinc pills.
- The study is suspended or canceled.

7. FINANCIAL INFORMATION

7.1 Who will pay for the cost of the study? Will I or my health plan be billed for any costs of the study?

There will be no health costs to you or your health plan for participation in this study.

You or your health plan will pay for all the things you would have paid for if you were not in the study, like:

- Health care given during the study as part of your regular care
- Standard deductibles or co-pays as part of your regular care

7.2 Will I be paid or given anything for taking part in this study?

You will receive a $30 merchandise card at each of the first 3 visits and a $60 dollar merchandise card at the final (4^{th}) visit to thank you for your participation. If you complete all 4 visits, this will be a total of $150 in merchandise cards.

7.3 Who could profit or financially benefit from the study results?

There is no profit or financial benefit to either the study participants or to the researchers conducting this study.

8. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

8.1 How will the researchers protect my privacy?

As part of this study, we will be collecting health information about you and sharing it with others. This information is "protected" because it is identifiable or "linked" to you. To protect your privacy, your samples will be labeled only with a study number that has been assigned to you. All information that links your name to your study number will be separated from other study information and secured within a locked cabinet at UNM. All study results in the database will be linked only to your study number and not to your name or any other identifying information. All data collected as part of this study will be entered into and stored in secure databases at UNM.

Local study liaisons will need access to your name and phone number to contact you, but they will not be able to see any of the study results from your samples.

All biological samples (blood and urine) will be stored in secure, temperature regulated facilities at UNM until analysis. Stored samples will be labeled only with PIN numbers and will not contain any personal identifiable information. Samples will be kept for 3 years beyond the end of the study to allow for any reanalysis to clarify results. Your samples will not be used for any other studies or for any reasons beyond what is described in this form. Any biological samples that remain after the analyses are complete will be destroyed and a specific certificate of destruction will be created and available to you if you want to receive it.

8.2 HIPAA Authorization for Use and Disclosure of Your Protected Health Information (HIPAA)

By signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. The researchers will obtain and use information from the surveys you fill out and from the blood and urine samples that you provide. This information could include:

- Information about where you live
- The amount of metals that you have in your blood and urine
- Biomarkers of autoimmunity or immune responses. This information is for research purposes only and is not intended to be used for diagnosis of sickness or disease.
- DNA damage and DNA repair measurements. This information is for research purposes only and is not intended to be used for diagnosis of sickness or disease.

The results of this study will be provided to the Navajo Nation Human Research Review Board and could be published in an article. The reports and articles will only include group-level results and will **NOT** include any identifiable information that would let anyone know who you are.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, it will include a summary of the results. You can search this website at any time.

If you give permission, you can receive the results from metals analysis of your blood and urine directly through the mail at an address you provide. This letter would contain your name, mailing address, and information about the metals found in your blood and urine. This information could be seen by someone other than yourself who might open your mail. We will not generate or send these letters without your permission as indicated in the check box below:

☐ **Yes, I would like to have the results of the metals analysis sent to me. I understand that others could see my name and address together with my metals results on the letter that is generated.**

☐ **No, I do not give permission for the research staff to generate a letter containing my results (I may change my mind later, and request a copy of my results by contacting research staff listed in section 9).**

8.3 What happens to information about me after the study is over or if I cancel my permission?

Sometimes information about you will be used or disclosed, even after you have canceled your permission or the study is over. Examples of reasons for this include:

- Your information was already included in study results before you canceled your permission.
- To help University and government officials make sure that the study was conducted properly.

Your information will be securely stored at UNM for three years after the completion of the study and then turned over to the Navajo Nation, without any identifying information such as names or addresses of study participants, pursuant to the Navajo Nation Human Research Code (1996).

8.4 When does the permission to use my information expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by calling or writing the researchers listed in Section 9 “Contact Information” (below).

9. CONTACT INFORMATION

9.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study treatments
- Report an illness, or other problem (you may also need to tell your regular doctor)
- Leave the study before it is finished
- Express a concern about the study

Contact information for Researchers:

Dr. Laurie Hudson – lhudson@salud.unm.edu 505-272-2482

Dr. Esther Erdei- eerdei@salud.unm.edu 505-272-4431

Dr. Debra MacKenzie- dmackenzie@salud.unm.edu 505-272-6535

Mr. Chris Shuey- sric.chris@gmail.com 505-262-1862

Contact Information for Consulting Physician:

Dr. Kathy Morsea, MD-Gallup Indian Medical Center (505)870-1570; (505)722-1000

SRIC Website – www.scric.org/Zinc

If you would like to speak with someone other than the research team, or if you have questions regarding your rights as a research subject, you may call the chair of the Navajo Nation Human Research Review Board, **Ms. Beverly Becenti-Pigman at (928) 871-6929**. You may also call the **UNM Health Sciences Center Human Research Protections Office (HRPO) at (505) 272-1129.**

10. CONSENT

You are making a decision to participate in this study. Your signature below indicates that you have read the information and the study was explained to you. By signing this consent form, you are not waiving any of your legal rights as a research subject.

Consent of Adult Participant

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, or providing verbal consent as witnessed below, I agree to participate in this study. I acknowledge that a copy of this consent form has been provided to me.

_____	_____	_____
Participant Name (print)	Signature	Date

Signature of Witness of verbal consent or translator- if utilized

_____	_____	_____
Name of Witness (print)	Signature	Date
_____	_____	_____
Name of Second Witness (print)	Signature	Date

Research Team Member Signature

I have explained the research to the prospective participant or his/her legal representative and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

_____	_____	_____
Name of Research Team Member (print)	Signature	Date