OFFICIAL TITLE:
Adaptation and Implementation of a Cherokee-based Participatory Research Project to Reduce CVD Risk

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CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Researcher's Name(s): Melissa Lewis
Project Number: 2097784

Project Title: Adaptation and Implementation of a Cherokee-based participatory research project to reduce CVD risk: Phase II

KEY INFORMATION ABOUT THE STUDY

You are invited to be in a research study about the impact of participating in the program called *Duyugoda igalenisodi*. Participants will be asked to answer questions about their health and their experience of the *Duyugoda igalenisodi* program in hopes of providing valuable feedback to so that the program may be improved or expanded as needed. You were selected as a possible participant in the research study because you will participate in the *Duyugoda igalenisodi* program. We ask that you read this form and ask any questions you may have before agreeing to be in the study. When you are invited to participate in research, you have the right to be informed about the study procedures so that you can decide whether you want to consent to participation. Please ask the researcher to explain any words or information that you do not understand.

You have the right to know what you will be asked to do so that you can decide whether or not to be in the study. Your participation in this research study is voluntary and does not affect your ability to participate in the *Duyugoda igalenisodi* program. You do not have to be in the study if you do not want to. You may refuse to be in the study, and nothing will happen. If you do not want to continue to be in the study, you may stop at any time without penalty or loss of benefits to which you are otherwise entitled.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate the *Duyugoda igalenisodi* program to determine if it impacts participant's health and well-being and to gather feedback from participants about their experience participating in the program.

HOW MANY PEOPLE WILL BE IN THE STUDY?

About 60 people will take part in this study.

WHAT AM I BEING ASKED TO DO?

If you agree to be in this study, we will ask you to do the following things: Complete an online survey regarding your health, well-being, cultural connection/identity, and satisfaction with the program. Specifically, you will be asked questions regarding your physical health-including diet and exercise. We will also take weight, height and blood pressure measurements; your mental/social health-including stress, distress, depression, and social support systems; your cultural connection/identity-including cultural and spiritual beliefs and behaviors and language; and your satisfaction with the program – including program acceptability, appropriateness, and feasibility. In total, this survey will take approximately 1 hour to complete. You will be asked to complete this survey 2 times: before you start the program and when it is finished. Further, you are being asked to give permission to use this data for research purposes. You can stop participating at any time without penalty.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

Your participation may result in the following benefits:
1) Increased personal awareness of the benefits of the *Duyugoda igalenisodi* program
2) Provide valuable feedback to improve the *Duyugoda igalenisodi* program and provide a worthwhile experience for other Cherokee participants
3) Increased feelings of pride in being part of an important piece of research that will help Cherokees and other tribal nations create positive intervention programs for their members

WHAT ARE THE RISKS OF BEING IN THE STUDY?

Risks of this study
Participants will be asked to answer questions about their health, well-being, cultural identity, and program satisfaction. The study has several risks, although the likelihood of risk is low. For instance, participation in this program assessment risks feelings of embarrassment or feeling uncomfortable depending on each person's experiences of the program and their level of comfort answering electronic questions about these experiences. Answering these questions may risk feelings of embarrassment, sadness, and frustration. Participants do not have to answer any question that they do not feel comfortable with. Further, questions are centered around their personal experiences and are not emotional or stressful in nature.

To help lower these possible risks, we will allow you to complete this survey in privacy, keep your information confidential and provide you with a list of healthcare providers if you may need them.

We will tell you about any new important information we learn that may affect your decision to continue to participate in this study.

WHAT ARE THE COSTS OF BEING IN THE STUDY?

There is no cost to you.

You should discuss any questions about costs with the researchers before agreeing to participate.

WHAT OTHER OPTIONS ARE THERE?

You have the option of not participating in this study and will not be penalized for your decision. You can simply choose not to participate.

CONFIDENTIALITY

The research team is committed to respecting your privacy and keeping your personal information confidential. We will make every effort to protect your information to the extent allowed by law. Information produced by this study will be stored in the investigator's file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the study in a form that could identify you without your written consent, except as required by law.

When the results of this research are shared, we will remove all identifying information so it will not be known who provided the information. Your information will be kept as secure as possible to prevent your identity from being disclosed.

What we collected from you as part of this research will not be used or shared for future research studies. It will only be used for purposes of this study.

WILL I BE COMPENSATED FOR PARTICIPATING IN THE STUDY?

You will receive payment for your time and participation totaling $50 at each of the two survey completion periods (October, June). You will receive this payment in the form of cash and a small gift to thank you for your participation at each survey completion. You will receive this payment and gift within approximately 4 weeks of your survey completion.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Participation in this study is voluntary. You do not have to participate in this study.

WHO DO I CONTACT IF I HAVE QUESTIONS, CONCERNS, OR COMPLAINTS?

The researcher conducting this study is: Dr. Melissa Lewis. Melissa is an enrolled member of the Cherokee Nation and an assistant professor in the department of Family & Community Medicine at the University of Missouri School of Medicine. You may ask any questions you have now. If you have questions later, **you are encouraged** to contact her about the research. Email: lewismeli@health.missouri.edu.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enroll or to continue to participate in this study, you may contact the University of Missouri Institutional Review Board (which is a group of people who review the research studies to protect participants' rights) at (573) 882-3181 or muresearchirb@missouri.edu, as well as, or Dr. Sohail Khan, Director of Health Research & Co-Chair Cherokee Nation IRB at (918) 453-5602 or Sohail-Khan@cherokee.org. If you want to talk privately about your rights or any issues related to your participation in this study, you can contact University of Missouri Research Participant Advocacy by calling 888-280-5002 (a free call), or emailing muresearchrpa@missouri.edu.

DO I GET A COPY OF THIS CONSENT?

You will receive a copy of this consent for your records.

We appreciate your consideration to participate in this study.

CONSENT SIGNATURES

I have read, understood, and printed a copy of, the above consent form and desire of my own free will to participate in this study.

I am 18 years or older **and** a citizen of either Cherokee Nation, United Keetowah Band of Cherokees, or Eastern Band of Cherokee Indians.

If the participant replies yes:

Subject's Signature:_____Date_____

[Electronic Signature]