Avera McKennan

Consent to Participate in a Research Study

Title:	Infant Care Practices Study – A clinical trial to assess the efficacy of a culturally appropriate infant sleep intervention
	NCT03494621
Funding Agency:	National Institutes of Health
Principal Investigator:	Amy Elliott, PhD
	Avera Center for Pediatric and Community Research
	605.504.3160

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A clinical trial to assess efficacy of a culturally appropriate infant safe sleep intervention

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PRINCIPAL INVESTIGATOR: **Amy Elliott, Ph.D.**
Avera Center for Pediatric and Community Research
Phone: (605) 504-3160

STATEMENT OF RESEARCH:
It is a basic ethical principle that a person taking part in research must give his or her informed consent to such participation. This consent must be based on the understanding of the nature and risks of the research. This document provides information important for this understanding. Research projects include only participants who choose to take part. Please take your time to make your decision. If at any time you have questions, please ask.

WHAT IS THE PURPOSE OF THIS STUDY?
The purpose of this study is to see if participation in a culturally appropriate program can promote the use of safe sleep practices for infants in American Indian communities. The program is called the *Is'time'pi Ichuan Owawicanyankapi* (Protecting Babies While They Sleep) Curriculum. This Curriculum is developed by getting information from community members on things people consider when choosing a sleep environment for babies. It includes brief videos featuring American Indian elders and medical professionals, and culturally based activities.

WHY HAVE YOU BEEN INVITED TO PARTICPATE IN THIS STUDY? You have been invited to participate in this study because you are a pregnant woman, identify yourself as American Indian and reside in Pine Ridge or Rapid City. We are also asking permission for your baby to participate in the study after birth.

HOW MANY PEOPLE WILL PARTICIPATE? Approximately 150 pregnant women from the Pine Ridge and Rapid City communities will be enrolled into the study. Seventy-five (75) women will be randomly assigned to receive the Curriculum and 75 will be assigned to a control group that does not receive the Curriculum. The control group receives other appropriate educational materials on pregnancy and infant care that are drawn from local health care facilities.

HOW LONG WILL I BE IN THIS STUDY? You and your baby's participation in the study will last until your baby is 12 months old. Your total participation will last approximately 1.5 years.

WHAT WILL HAPPEN DURING THIS STUDY? If you decide to participate, you will be randomly assigned to an intervention group or a control group. Random assignment is a procedure in which each participant has an equal chance of being in the intervention group or the control group. The assessments in the study will begin during your pregnancy and continue until your baby is 12 months old.

During Pregnancy. You will have three contacts with the research staff during pregnancy. At these contacts we will collect basic demographic information such as age, household income, education, employment; medical and reproductive history and information on social support, knowledge of infant safe sleep practices and questions about your plan and ability to provide a safe sleep environment for your baby. If you are enrolled in the intervention group, you will take part in the activities related to the Curriculum. If you are enrolled in the control group, you will receive an array of educational materials on pregnancy and infant care. These materials will be drawn from information currently available from local health care facilities such as

Native Women's' Health care, other local OB/GYN facilities, and the South Dakota Department of Health. At the third prenatal contact, you will be invited to bring up to two adult family members or support persons to the session.

Delivery visit. You will have six contacts with the research staff after the birth of your baby. The first contact will be at the hospital. If you are enrolled in the intervention group, you will take part in the activities related to the Curriculum. You will also receive an infant sleep area of your choice such as a portable bassinet or Pack 'n' Play. If you are in the control group, you will receive educational materials related to pregnancy and infant care. You will also receive a celebratory gift basket with items for your use such as a reusable water bottle and for your baby's use such as infant sleepers.

Medical Records. We would like to look at both your medical records and your baby's. We will copy some information from these records. We will look for information about your pregnancy and information about your baby's medical care. Only study staff will have direct access to your and your baby's medical record.

After discharge. You will visit the research staff several times until your baby is one year of age. These contacts include a telephone call at 1 month, a home visit at 3 months, an office visit at 6 months, and follow-up contact via a letter and phone call at 9 and 12 months respectively. At the home visit we will ask you to show us your baby's sleep environment and answer some questions related to your baby's sleep habits. With your permission, we may take photographs of your baby in his or her sleep area. If you are enrolled in the intervention group, you will be asked questions regarding your infant sleep practices and to engage in the Curriculum activities. If you are in the control group, we will review appropriate educational information on maternal and infant care. The follow-up contacts will help us stay in touch with you and update your contact information.

WHAT ARE THE RISKS OF THE STUDY? There may be unforeseeable risks to you and your baby during pregnancy and in the future after birth, but it is very unlikely. Any risk from being in this study is not expected to be more than risk experienced in everyday life. You may experience frustration that is often experienced when completing surveys. Some of the questions related to your mental health may be of a sensitive nature and you may become upset as a result. If you become upset by questions, you may stop at any time or choose not to answer a question. If you would like to talk to someone about your feelings or concerns, we may offer to find someone who can help, such as a mental health resource. The study will not pay for additional help. There is a slight risk of loss of confidentiality. To minimize this risk, we will keep all study information protected at all times. If you would like to talk to someone about your feelings regarding this study, you may call the Principal Investigator, Amy Elliott, at (605) 504-3160.

WHAT HAPPENS IF YOU OR YOUR BABY IS INJURED? 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 an injury. If you feel that you or your baby have suffered a research-related injury, contact Dr. Amy Elliott at (605) 504-3160.

WHAT ARE THE BENEFITS OF THE STUDY? Research participants may or may not receive direct benefits from this project. We believe that the knowledge to be gained about efficacy of a culturally driven safe sleep intervention will have far reaching positive effects on the health and safety of infants in American Indian communities.

WHAT ARE THE ALTERNATIVES TO PARTICIPATING IN THIS STUDY? The alternative is to not participate in this study.

IS THIS STUDY VOLUNTARY? Your participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you or your baby are otherwise entitled. Any significant new findings developed during the course of this research, which may relate to your willingness to continue study participation, will be provided to you. If you wish to leave the study, you may do so by notifying the research staff, either in person, verbally, or in writing. Information collected from you prior to the point of withdrawal will be used by the study. Withdrawing from the study will not affect your current or future relations with Avera McKennan.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY? There are no costs to participants in this research project.

WILL I BE PAID FOR PARTICIPATING? You will be compensated for your time in the study. You will receive a $25 gift card at the end of each of your in-person visits. Additionally, you will receive a pack of diapers at all in-person, postnatal visits. Upon request, transportation assistance will be provided. You will receive a $10 gift card for each telephone visit after it is completed. Gift cards for telephone visits may be either picked up in the study office or mailed to your address.

WHO IS FUNDING THE STUDY? The study is being funded by the National Institutes of Health.

WHAT ARE MY RIGHTS AS A PARTICIPANT? Taking part in this study is voluntary. You have the right to:

- Refuse to participate in this study
- Skip any questions or stop any task or interview before it is finished
- Withdraw from the study at any time

CAN I BE REMOVED FROM THE STUDY? If you do not meet study eligibility criteria at this time, we will remove you from the study. All information collected will be securely destroyed. If we feel that having you continue in the research study would not be good for you or your baby, or if you no longer meet eligibility criteria during your participation in the study, we will remove you and your baby from the study. This removal may happen without your consent. All information collected up until the point of removal will be used in the study.

ARE MY RECORDS CONFIDENTIAL? The records of this study will be kept confidential to the extent required by law. In any report about this study that might be published, you will not be identified. Your study record may be reviewed by the National Institutes of Health, Avera Human Research Protection Program, the Avera Institutional Review Board, the Oglala Sioux Tribe Research Review Board, the Regional Health Institutional Review Board, and the Great Plains Indian Health Service Institutional Review Board. Confidentiality of the data will be maintained at all times. All paper data from the study will be stored in locked filing cabinets at the clinical sites. Electronic files will be stored in a password protected database secured with standard SSL (Secure Socket Layer) encryptions.

WHOM MAY I CONTACT IF I HAVE QUESTIONS? You may call this number if you need to change your appointment or if you have questions, concerns, or complaints about the research: Avera Center for Pediatric and Community Research, (605) 504-3154.
If you have questions regarding your rights as a research subject, or would like to offer input, you may contact the Avera Institutional Review Board (IRB) at (605) 355-4706, the Oglala Sioux Tribe Research Review Board at (605) 867-1704, or the Great Plains Area Indian Health Service IRB at (866) 331-5794. An IRB is a group of people who review the research to protect your rights and welfare.

- You may also call these numbers about any problems, complaints, or concerns you have about this research study.

- You may also call these numbers if you cannot reach research staff, or you wish to talk with someone who is independent of the research team.

CLINICAL TRIAL REGISTRATION: A description of this clinical trial will be available on http:// www.clinical trials.gov, as required by US law. The website will not include information that can identify you or your baby. At most, the Web site will include a summary of results. You can search this Website at any time.

WHAT ABOUT FUTURE STUDIES? We would like to be able to contact you in the future about other studies that may be conducted. Participating in the study today in no way obliges you to participate in future studies.

Please initial ONLY ONE of the following:

_____ Yes, I agree to be contacted in the future

_____ No, I do not wish to be contacted in the future

PERMISSION TO TAKE PHOTOGRAPHS: Pictures will only be used for research purposes, and neither you nor your baby will be identified in any publication.

Please initial ONLY ONE of the following:

_____ Yes, I agree to have photographs taken of my child

_____ No, I do not wish to have photographs taken of my child

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You also give permission for your baby to take part in this study after birth. You will receive a copy of this form.

_____ _____
Printed name of the participant Date of birth

_____ _____
Signature of participant Date

I have explained the risks and benefits and the procedures involved with participation in this study.

_____ _____
Signature of study representative Date