SOUTH DAKOTA STATE UNIVERSITY

CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

Anthropometry in Children: An investigation into different methods of length and limb measurement in children from birth to 8 years.

I. INTRODUCTION

I have been invited for my child to participate in a research study. Before agreeing to allow my child to participate in this study, it is important that I read and understand the following explanation. It describes the purpose, procedures, benefits and risks of the study. It also describes the right to withdraw from the study at any time.

II. PURPOSE

The purpose of this project is to determine the effectiveness of different arm and leg measurements as predictors of length and height in infants and children aged 0 to 8 years.

I, _____, of _____, _____, _____,

(Name) (Street address) (City) (State)

voluntarily consent to have my child participate in a research study, the purpose of which is to assess alternative methods of determining length and height based off measurements of arm and leg length. I understand that I can withdraw from the study with the penalty.

III. PROCEDURES

1. I will be contacted either by phone, e-mail, or in person to schedule a visit.
2. My child's length or height will be measured using standard equipment which could be used in a doctor's office or clinic and the length of my child's arm and leg will be measured using a special ruler.

IV. BENEFITS & COMPENSATION: There is no cost for me to participate in the study. When measurements are taken on my child, I will receive $25.

V. RISKS: There are no risks associated with these activities.

VI. CONFIDENTIALITY OF RECORDS AND ALTERNATIVES

Once all information is collected my child's name and date of birth will be deleted from the files and they will not be identified in any manner. Only study personnel will be allowed access to data which will be maintained in a locked filing cabinet.

I understand that I can decide not to have my child participate at any time and that I am free to withdraw them from the study.

A copy of the consent form will be given to me to keep.

Any questions concerning the study can be answered by Bonny Specker, Ph.D. at 688-4645 or Norm Braaten SDSU Human Subjects Committee Administrator at 688-6975.

SIGNATURES:

_____(Participant)_____(Date)

_____(Investigator)_____(Date)

SOUTH DAKOTA STATE UNIVERSITY

CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

Anthropometry in Children: Limb length vs. DXA measurements

I. INTRODUCTION

I have been invited for my child to participate in a research study. Before agreeing to allow my child to participate in this study, it is important that I read and understand the following explanation. It describes the purpose, procedures, benefits and risks of the study. It also describes the right to withdraw from the study at any time.

II. PURPOSE

1. Determine the effectiveness of different arm and leg measurements as predictors of length and height in infants and children aged 0 to 8 years.
2. To determine the accuracy of the arm and leg measurements for assessing growth by comparing ruler measurements with measurements obtained by a bone imager.

I, _____, _____, _____, _____,
(Name) (Street address) (City) (State)

voluntarily consent to have my child participate in a research study, the purpose of which is to assess alternative methods of determining length and height based off measurements of the arm and leg. I understand that I may leave the study at any time with no penalty.

III. PROCEDURES

1. I will be contacted either by phone, e-mail, or in person to schedule a visit.
2. My child's length or height will be measured using standard equipment which could be used in a doctor's office or clinic and the length of my child's arm and leg will be measured using a special ruler.
3. A machine (DXA bone imager) will be used to measure the length of my child's arm and leg bones. The test will take place at the Ethel Austin Martin Building on the campus of South Dakota State University or in a mobile research unit.

IV. BENEFITS AND COMPENSATION: There is no cost for me to participate in the study. When measurements are taken on my child, I will receive $25.00.

V. RISKS: The bone scans involve the use of x-rays. This procedure has an estimated effective dose of 1 millirem (mRem). This is less than the effective dose received during a normal chest X-ray (5.0 mRem) or a transcontinental round trip flight (5.0 mRem). The effective dose is also within the negligible individual risk limit of 1 mRem which has been established by the National Council for Radiation Protection. The FDA also has regulations regarding the maximum acceptable effective dose which is allowable from medical research in children. These regulations are a single whole body dose of 300 mRem or an annual whole body dose of 500 mRem. Based on this information, your child is at no greater than minimal risk by participating in this project.

VI. CONFIDENTIALITY OF RECORDS AND ALTERNATIVES

Once all information is collected my child's name and date of birth will be deleted from the files and they will not be identified in any manner. Only study personnel will be allowed access to data which will be maintained in a locked filing cabinet.

I understand that I can decide not to have my child participate at any time and that I am free to withdraw them from the study.

A copy of the consent form will be given to me to keep.

Any questions concerning the study can be answered by Bonny Specker, Ph.D. at 688-4645 or Norm Braaten SDSU Human Subjects Committee Administrator at 688-6975.

SIGNATURES:

_____ _____
Parent or Legal Guardian Date

_____ _____
Additional Parent or Legal Guardian Date

_____ _____
Study Representative Date