Reliability of Sacral Slope, Pelvic Femoral Motion and Cup Ante-inclination on AP Pelvic Radiographs in Healthy Pts

2/19/2025

IRB: 0719-20-FB

NCT04687306

CONSENT FORM
Adult Consent Form

Title of this Research Study
Inter-Observer

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Nebraska (CN).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

The purpose of this research study is to find ways to measure images or x-rays that can help find hip and spine problems in the future in young healthy people.

At this time there is no testing that can be done to foresee the risk of future pelvic spine issues. This study will measure three different angles through x-rays of you while sitting and standing.

This study will enroll healthy males and females between the ages of 25 and 50 and without a history of spinal and/or lower limb problems.

By participating you may help investigators determine if x-rays could be a future predictor if someone will or will not have spinal pelvic issues in the future.

The most serious risk in this study is the exposure of radiation. The radiation dose is small and can be compared to 6 months of outdoor exposure.

Instead of being in the study you can choose to not participate.

Why are you being asked to be in this research study?
You are being asked to be in this study because you are 25 - 50 years of age and are

healthy without spine/hip/pelvis issues. You have not had any previous injuries or surgeries to these areas.

There will be up to 30 subjects enrolled to complete the study at this institution. If you are pregnant, you cannot participate.

What is the reason for doing this research study?
The purpose of this study is to find ways to measure images or x-rays that can help find hip and spine problems in the future in young healthy individuals.

What will be done during this research study?
This is a one-time only study visit, two visits if females who have a pregnancy test choose to return for x-rays rather than wait for pregnancy test results. Two x-ray images will be performed on each subject, one will be taken while sitting and the other will be taken while standing. This study will measure three different angles through x-rays of you while sitting and standing. The x-rays will be evaluated for the three measurements by four individuals with the intent of evaluating inter-observer reliability (consistent measurements by different persons).

Females of childbearing potential must provide a negative urine pregnancy test to participate. This lab collection and processing can be done in the same visit if the subject wishes to wait for results.

Consenting is expected to take under 20 minutes; to offer a urine sample at the lab for pregnancy testing is expected to take about 10 minutes; checking into radiology, changing into gown and completing the radiographs is expected to 30 minutes, (If a female wishes to complete everything in one visit, the wait time for the pregnancy test which needs to be transported by courier from Lauritzen Outpatient Care Center to main lab may take up to 2 hours).

What are the possible risks of being in this research study?
The most serious risk in this study is the exposure of radiation. The radiation dose is small and can be compared to 6 months of outdoor exposure.

There is a possible risk of a loss of confidentiality (your personal data), but there is a plan in place to prevent this from happening.

If you are a female of childbearing potential, you may discover you are pregnant.

What are the possible benefits to you?

You are not expected to get any benefit from being in this research study. The results from the pelvis and spine x-rays will be part of your medical record. If any unusual results are indicated on the x-rays, the principal investigator will discuss the results with you.

What are the possible benefits to other people?
An increase in knowledge and to find new ways of measuring pelvic motion for risk of future problems.

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to take part.

What will being in this research study cost you?
There is no cost to you to be in this research study.

Will you be paid for being in this research study?
If you choose to participate in this study, you will be offered a gift card in the amount of $25.00 for time and travel. Women of child bearing potential who require a pregnancy test and have to wait for results or choose to return for xrays will receive a $40 gift certificate.

Who is paying for this research?
There is a support to fund this study by UNMC organization and the UNMC department of Orthopaedics.

What should you do if you are injured or have a medical problem during this research study?
Your health and safety is our main concern. If you are injured or have a medical problem because of this study call someone listed at the end of this consent form. You can get emergency medical treatment at Nebraska Medicine. You can also go to your doctor, the nearest emergency room or call 9-1-1.

We have no plans to pay for your treatment or give you any other money or compensation. Your insurance may pay. If they do not you will have to pay.

Signing this does not mean you have given up any of your legal rights.

How will information about you be protected?
In the course of this research we may collect information about you. This can be things that could be used to find out who you are (like your name, phone number,

birthdate, address). We call this "identifiable private information". We will keep this information as confidential as possible.

Who can see information about you?
We also will get medical information about you (like medical record number, medical history, or the results of physical exams, blood tests, x-rays or other medical or research procedures). We call this "protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your PHI as confidential as possible.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your PHI. Your PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your PHI, you will have to stop being in this research.

We may share your PHI with other groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- The HHS Office for Human Research Protections (OHRP)

We may share your PHI with other groups listed below. The HIPAA Privacy Rule requires these groups to protect your PHI.

- Researchers at UNMC/Nebraska Medicine involved in the study
- Your health insurance company

You are letting us use and share your research data for as long as the research is going on.

How will results of the research be made available to you during and after the study is finished?
In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address:

Department of Orthopaedic Surgery
Kevin Garvin, M.D.
985640 Nebraska Medical Center
Omaha, NE 68105

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

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or the organization. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop being in this research (withdraw) at any time. Just call the researcher or any research staff. Any research data we have already collected can still be used in the research.

Will you be given any important information during the study?
We will tell you right away if we get any new information that might make you change your mind about being in the study.

What should you do if you have any questions about the study?
We gave you a copy of *"What Do I Need to Know Before Being in a Research Study?"* If you ever have any questions about this study, call the Principal Investigator or anyone else listed on this consent form.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research,

you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
  - Telephone: (402) 559-6463
  - Email: IRBORA@unmc.edu
  - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
  - Telephone: (402) 559-6941
  - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are deciding whether to be in this research study. Signing means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject_____ Date_____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate

Signature of Person Obtaining Consent_____
Date_____

Authorized Study Personnel
Principal
* Garvin, Kevin
phone: 402-559-5605
alt #: 402-559-8000
degree: MD

Secondary

* Kildow, Beau
phone: 402-552-9653
alt #: 402-559-8000
degree: MD

* Vincent, Scott
phone: 402-559-9171
alt #: 402-559-8000
degree: MD

Lead Coordinator

* Danielson, Pete
phone: 402-559-1703
alt #: 402-559-1703
degree: BS

Other Coordinator

* Schwarz, Dana
phone: 402-559-4167
alt #: 402-559-4167
degree: RN, MS