Procedure language:

DXA (Dual Energy X-ray Absorptiometry): Participants will be asked to lie supine on the DXA table for 6-9 minutes.  Measures of total body composition (percent body fat and percent body lean mass) and bone mineral density will be performed.  Immediately prior to DXA assessment in pre- or peri-menopausal women, a pregnancy test by urine with confirmation of a negative result will be required (none are anticipated for the second study).  A member of the research team will visually verify the result after completion of the pregnancy test. The urine pregnancy test screens for human chorionic gonadotropin (HCG).  Current evidence indicates that this test ranges in accuracy from 75-97.4% depending upon time of test relative to actual fertilization.  To further protect against false-negative results, the urine test is complimented by screening for menstrual status and potential pregnancy or planned pregnancy through the UWHHSQ.  If a woman becomes pregnant prior to completion of the study, she will be excluded from further participation and DXA testing. The collaborating Medical Director has authorized DXA scans and will have access to review each participant's scan for clinical indications (i.e. low bone mineral density), which may or may not warrant additional follow-up from an outside health care provider.  The investigative team has completed the required University of Wyoming X-ray Safety Training and DEXA training and is approved by the university to conduct DXA scans for research purposes.  They will be the only researchers conducting DXA scans.  All DXA records will be available to the university Risk Management and Safety Office for compliance/safety review. Only the whole-body scan will be performed during each DXA test.

Risk language:

There is some risk associated with the radiation received during usage of the dual energy X-ray absorptiometry (DXA) scan used for body composition testing.  The more radiation received throughout life, the greater the risk of having cancerous tumors or of inducing changes in genes.  Changes in genes could possibly cause abnormalities or disease in offspring.  The radiation in this study is not expected to greatly increase these risks, but the exact increase in such risks is unclear.  However, the amount of radiation received during a DXA test (as reported by the equipment manufacturer) is less than 0.1 mrem for a single whole-body scan. This is about the same as four (4) hours of normal background radiation, or about 1/100th of a typical dental x-ray.  This type of x-ray is routinely performed for research, diagnostic, and clinical purposes and has been deemed appropriate for clinical research.  Pregnancy presents additional risk and women of childbearing age/potential must complete a pregnancy test (with negative result) prior to a DXA scan.  Pregnancy excludes participating in a DXA scan.  An inherent risk is a false-negative urine pregnancy test; this risk is minimized by also conducting a verbal screening for potential pregnancy or planned pregnancy.

A pregnancy test will be administered prior to the DXA scan.  In the case of a positive test, the participant will be informed and referred to their health care provider and provided with contact information for other medical resources including;

1.      University of Wyoming Student Health Services

2.      Ivinson Memorial Hospital

3.      Laramie Reproductive Health - Family Planning center

4.      Laramie Physicians for Women and Children

Should the participant express/experience emotional/psychological distress, they will be referred to their health care provider, the University of Wyoming Counseling Center, or Ivinson Memorial Hospital's Behavioral Health center.

Informed Consent language:

Qualification:

You are not pregnant or trying to become pregnant

Procedure:

\*      Measuring your height, weight, waist girth, the percentage of lean and fat mass you have, and how strong your bones are.  To measure your muscle and bone health, you will lie on an x-ray table for about 6 minutes while a low-level X-ray scan is performed.

Risk statement:

There is some risk associated with the radiation received during the dual energy X-ray absorptiometry (DXA) scan. However, the amount of radiation received (as reported by the equipment manufacturer) is less than 0.1 mrem for a single whole-body scan. This is about the same as four (4) hours of normal background radiation, or about 1/100th of a typical dental X-ray.  The radiation in this study is not expected to greatly increase any risks associated with radiation exposure, but the exact increase (if any) is unclear.  This type of X-ray is routinely performed for research, diagnostic, and clinical purposes and has been deemed appropriate for clinical research.  Pregnancy presents additional risk.  Female participants of childbearing age/potential will be required to complete a urine pregnancy test (with negative result) prior to the DXA scan.  In the case of a positive test, the DXA scan will not be performed and you may be disqualified from this research.  Please inform the research team if you could be pregnant or are trying to become pregnant.