

**Division of Nutritional Sciences (DNS)
Human Metabolic Research Unit (HMRU)
Standard Operating Procedure**

Dual Energy X-Ray Absorptiometry (DXA)

Intent of Service:

Research conducted in the HMRU occasionally requires that bone density and/or body composition be obtained in human participants via a DXA scan. This scan is conducted in the HMRU DXA Laboratory which contains a Hologic Discovery-A DXA scanner that is capable of measuring site specific or whole body bone density, vertebral fracture risk and body composition. This unit also has the capacity to scan neonates for bone density and body composition. The DXA Lab contains the DXA scanner, a computer station for operation of the equipment and a changing table and rocking chair to accommodate mother/infant study participants.

Participants:

All research conducted in the HMRU, including those studies requiring a DXA scan, must be approved by Cornell's Internal Review Board (IRB). All female participants between the ages of 11 and 55 are required to have urine pregnancy test and to sign a consent form that has been approved by the IRB before having this test in the HMRU.

Licensing:

The DXA facility has been certified by the State of New York and has a permit for its operation. Cornell University's Environmental Health and Safety (EHS) oversee this facility and provide the required permit and training related to radiation exposure associated with the use of this equipment. All DXA tests are performed by a Licensed Radiologic Technologist (LRT). EHS certifies this person according to University Guidelines related to the use of the DXA and issues this individual a radiation badge for monitoring purposes.

Procedures:

1. In advance of the DXA scan the Principal Investigator (PI) will provide the human participant with the attached DXA Information Sheet, Questionnaire, and the Consent Form approved by the IRB explaining that these documents should be reviewed and completed the day of the scan.
2. The PI or his or her designee will review these documents with the human participant, ask the human participant if they have any questions, and obtain written consent.
3. On the day of the DXA scan the LRT will confirm the identity of the human participant by asking their name. The LRT will obtain their height and weight and record this information on their questionnaire.
4. The LRT will provide any female human participant between the ages of 11 and 55 with a urine pregnancy test kit. If the test is positive the LRT will inform the participant and refer them to their personal physician. If the test is negative the LRT will confirm the negative result by signing the Questionnaire. A DXA scan will not be performed on any female who tests positive for pregnancy.
5. The LRT will review and update the quality compliance log documenting operation and stability of DXA based on the daily/weekly DXA phantom scans.

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6. The LRT will ask the subject to remove jewelry, body piercings, clothing with zippers or metal buttons, etc. and to put on a gown or other unrestrictive clothing for the scan.
7. LRT will position the patient on the DXA table and explain the procedure requesting that the patient remain still during the entire scan.

Equipment and Supplies:

DXA, urine pregnancy test for female subjects ages 11-55, exam gown (optional), all positioning aids needed for site specific DXA scans.

Service Providers:

All DXA scans in humans will be undertaken by a Radiologic Technologist licensed by the New York State Department of Health who has fulfilled all training requirements as mandated by Cornell University's Environmental Health and Safety.

Potential Risks:

There are no known risks associated with the amount of radiation provided by the DXA scan.

Preventive Measures:

1. All DXA tests are performed by a Licensed Radiologic Technologist (LRT).
2. All human participants will be provided with an Information Sheet on DXA and be asked to complete a Participant Questionnaire.
3. All female human participants aged 11 to 55 years will be given a urine pregnancy test immediately preceding their DXA scan. Female's testing positive for pregnancy will be informed of their positive test by the LRT, referred to their personal physician, and will not receive a DXA scan.
4. Take all precautions necessary when positioning subjects on the DXA table.
5. Any Cornell University faculty/staff/students involved with human participants in the HMRU for a DXA scan will have completed human subjects training.
6. The DXA facility has been certified by the State of New York and has a permit for its operation.
7. Cornell University's Environmental Health and Safety (EHS) oversee the DNS DXA Laboratory, provides the required permit and training related to radiation exposure associated with the use of the DXA, and monitors the amount of radiation emitted via radiation badges provided to the LRT and affixed to locations surrounding the DXA.

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Information Sheet

Research conducted in the HMRU occasionally requires that bone density and/or body composition be obtained in human participants via DXA. This DXA scan is conducted in the HMRU DXA Lab which contains a Hologic Discovery-A DXA scanner that is capable of measuring site specific or whole body bone density, vertebral fracture risk and body composition. This unit also has the capacity to scan neonates for bone density and body composition.

DXA is a method used to measure body composition. This procedure uses x-rays that yield precise, high quality images of your body compartments (e.g., fat and muscle tissues) that involves exposure to very low amounts of x-ray radiation. For all radiation sources, the standard measure of radiation dose to our bodies is called the Sievert (Sv) or millisievert (mSv) where 1 Sv is equal to 1000 mSv. Every person is exposed daily to natural background radiation from sources like soil, rocks, radon, and natural radiation in our bodies, the sun, and outer space. On average, a person in the United States receives about 3 mSv from natural background radiation, or about 0.01 mSv per day. When a person receives radiation as part of a research study at Cornell, their extra radiation dose is limited by Cornell to 1 mSv, which is the annual regulatory limit for the general public. Children under the age of 18 are limited to 0.1 mSv per year.

Example of Radiation Dosages:

Annual Background Radiation	3 mSv	Mammogram	0.06 mSv
CAT scan	10 mSv	DXA AP spine scan	0.07 mSv
Chest X-ray	0.08 mSv	DXA Whole Body scan	0.01 – 0.04 mSv
Roundtrip Transatlantic Flight	0.08 mSv	DXA Infant Whole Body Scan	0.012 mSv

Risks of Research Radiation: The amount of radiation exposure received in this study is below the levels that are thought to result in a significant risk of harmful effects. One possible indirect effect is an increase in the risk of cancer. The potential increase in the risk of cancer or potential increased risk of other adverse health consequences, from the low level of radiation used in this study is too small to be estimated accurately. If you have additional questions, please contact the research staff or Environmental Health & Safety at 607-255-8200 or at the EH&S web site: <http://www.ehs.cornell.edu/>.

What will be Expected of You: You must be able to lie still on a padded table and breathe normally for the duration of the scan which is approximately 6 minutes. The table will move horizontally and vertically during the scan. You will be asked to remove jewelry, body piercings, clothing with

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zippers or metal buttons, etc. and to put on a gown or other unrestrictive clothing for the scan. You may bring your own unrestrictive clothing with you or if you prefer you can use one of the HMRU gowns.

Before you arrive for your scan at the Human Metabolic Research Unit (HMRU) it's important that you read this document and the attached questionnaire and consent form. The questionnaire and consent form should be completed immediately before your scan. The Consent Form must be signed in the presence of the Principal Investigator.

Results of DXA Scan: The DXA machine will automatically generate a report of body composition for each scan. The analysis is based on a standard operating procedure for body composition analysis designed by the manufacturer of the DXA scanner. Research scans are not read by a radiologist. You may request a copy of this report from the Principal Investigator.

Pregnancy Testing: Because you are a female of childbearing age, you will be asked to take a urine pregnancy test. The DXA technologist must obtain the results of the pregnancy test before administering the scan. The test will be performed immediately preceding your scan. If the test is positive, the DXA technician will inform you that your test is positive and will not perform the scan.

Recent Previous Procedures: DXA should not be performed on participants who have had any procedure that included Iodine, Barium or Nuclear Medicine Isotopes within the last 7 days. Please inform us if this is the case.

Previous Surgery, Prosthetic Devices and Foreign Bodies: Since the body composition assessment involves a scan of the whole body, it is important to disclose any surgeries you may have had since they might impact the results of the DXA scan. For example, it is important to know if you have a prosthetic device, pacemaker leads, radioactive seeds, metal implants, or surgical staples. The same caution is also given to foreign bodies such as shrapnel and radio-opaque catheters or tubes.

Calcium Supplements: Calcium supplements should not be taken the day before the exam because they may interfere with the accuracy of the results. Please refrain from taking calcium for 24 – 36 hours before the DXA scan.

General Requirements for DXA scans: Physical and hydration factors may affect the results of the scan and therefore, we ask that you ensure that you:

- are able to lie still on a padded table and breathe normally for approximately 6 minutes;
- weigh less than 450 pounds (204 kg);
- wear clothing with no metal and remove all jewelry during the procedure;
- refrain from heavy exercise 12 hours prior to study;
- consume no alcohol, nicotine, or caffeinated beverages 12 hours prior to study;
- fast for at least 2 hours prior to study with only light meals in the 10 hours prior to fasting; and
- that you wear no deodorant or talcum powder the day of the exam.

Please make every effort to meet these criteria since they are important for the accuracy of the scan.

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Thank you!

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Questionnaire

Please bring this form with you to your appointment in the HMRU and answer the questions below **just before your scheduled scan**. If you have any questions, please ask the Principal Investigator or the Licensed Radiologic Technologist that will be performing your scan.

Name	
Date	
Date of Birth	
Age	

Have you had any X-ray procedures within the last 7 days which used:

Iodine	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Barium	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Nuclear Medicine Isotopes	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

Do you have any of the following medical devices in your body:

Ostomy Devices	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Prosthetic Devices	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Surgical Devices	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Pacemaker Leads	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Radioactive Seeds	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Radiopaque Catheters or Tubes	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

Do you have any of the following foreign objects in your body:

Shrapnel, Buckshot	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Metal of any Sort	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Other - Please Specify	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

Have you engaged in any of these activities in the past 12 hours:

Consumed Alcohol, Nicotine, or Caffeinated Beverages	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Exercised Heavily	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Taken Calcium Supplements	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

I have read the Information Sheet , have been encouraged to ask questions, and have received answers to my questions.

Name

Date/Time

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Official Use Only:

Weight	
Height	

I hereby certify that I have reviewed the pregnancy test for this patient and the test is negative.

Karla L. Golden
Radiologic Technologist
NYS License Number 876128

Date/Time