

Guidelines and Checklists for Preparing an IRB Application for a Project Involving DEXA Equipment

A. Research Personnel Information

List all personnel involved with this research who will have contact with human subjects or with their identifiable data. All personnel listed here must complete CITI training; everyone involved in DEXA procedures must complete Health and Safety training as well.

NAME	FACULTY OR STAFF	GRADUATE STUDENT	UNDERGRAD STUDENT	ROLE ON PROJECT*
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

* Be specific: PI, DXA technician, draw blood, data entry, data analysis, recruitment interviews, run reports, etc.

B. Training Checklist*

	YES	NO	N/A
1. All research personnel have completed the appropriate CITI course(s)	<input type="checkbox"/>	<input type="checkbox"/>	
2. All individuals, if required for their roles, have completed and have current:			
a. Bio Safety training	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Radiation Devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Radiation Devices Refresher	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*Training information can be found on the IRB website: <https://www.research.olemiss.edu/irb/education>

The use of pregnancy testing is not a requirement for DEXA protocols with female participants. However, a screening question for pregnancy, as well as the consent form language below, must be used.

If a potential participant states if they are not sure if they are pregnant, instruct them that they cannot move forward in the study at that time but can return in the future, if they are able to meet the criteria.

C. Suggested Language to use with [Consent Form Template](#)

[**Note:** *Italicized* words and phrases may or may not apply to your study. **Highlighted** language is required if female participants will be used]

Description

The purpose of this research study is _____. We will measure your height, weight, *body composition (percentage body fat)* and bone mineral density (or BMD). We measure *body composition and BMD* with a Dual Energy X-ray Array (DEXA), a medical device that exposes you to a low dose of radiation (– about 1/10 of the radiation from a chest x-ray and about as much radiation as you get from the sun from flying coast to coast)

DEXA Scan Procedure :

- 1) Remove all metal objects, including clothing containing metal
- 2) Remove at least your outer clothes and change into shorts and a t-shirt or wear a hospital gown
- 3) Measure height & weight
- 4) Lie on the DEXA padded table
- 5) A research technician will position your body on the table
- 6) Lie still for about 30 seconds during each of two scans (hip and spine) *and for about 6 minutes for the body composition scan*
- 7) Receive DEXA results (and an opportunity to sign a release form to fax results to your physician)

Risks and Benefits

Risks: *The amount of radiation used during a DEXA scan is considered safe for adults but can cause damage to unborn babies. If you are pregnant or think you could be pregnant, you are **not** eligible to participate in this study.*

Some people experience anxiety during this test, just like any medical test.

Benefits: *One benefit is that you will find out your percentage of body fat and how it compares to most other people. You will also find out if your bone mineral density (a contributor to bone strength) is within normal limits. If your bone mineral density appears to be low, we can fax the DEXA results to your physician with your written permission.*

D. DEXA Test Results Report Form

DEXA Test Results Report Form

Name of Subject _____ Date of DEXA scan _____

Based on guidelines established by the World Health Organization, the results of your DEXA scan indicate that you have a lower than desired bone mineral density. I recommend you make an appointment with your physician at your earliest convenience to discuss the results of this test. If you desire, we will fax a copy of these results to your physician.

Recommendation of:

Dr. Marshall Crowther, MD.
Supervising Physician
Center for Health & Sport Performance
The University of Mississippi

By signing my name below, I acknowledge that I have been advised that the results of my DEXA scan indicate that I have a lower than desired bone mineral density. My signature also acknowledges that I have indicated whether I request a copy of these test results be faxed to my physician.

____ Yes, I request a copy of my test results be faxed to my physician.

____ No, I do not request a copy of my test results be faxed to my physician.

My physician's name _____

Office location _____

fax number _____ phone number _____

____ Date _____

Signature of Participant

____ Date _____

Signature of Witness