**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\* |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| \* 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) |  |  |  |
| 2. All individuals, if required for their roles, have completed and have current: |  |  |  |
| a. Bio Safety training |  |  |  |
| b. Radiation Devices |  |  |  |
| c. Radiation Devices Refresher |  |  |  |

**\***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**](https://www.research.olemiss.edu/sites/default/files/NEW%20ADULT%20CONSENT%20FORM%20TEMPLATE-non-treatment%20studies_1.docx)

[**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.*

You will be provided with a copy of your scans so that you can provide them to your doctor if you wish.