| Sponsor: | Samumed | Protocol Number: | SM04690-OA-06 |
|---|---|---|---|

## VISIT SCHEDULE

| Protocol Time Point | Screening (V2) | Week 24 | Week 52 (EOS/ET)[1] |
|---|---|---|---|
| Lumbar Spine | X | X | X |
| Left Femur | X | X | X |
| Right Femur | X | X | X |

[1] All subjects who discontinue study drug early will be encouraged to complete study procedures thereafter for the duration of the study. If not done, early termination (EOS/ET) procedures should be performed at the time of discontinuation.

## DXA SCAN ACQUISITION MODES

**Each data shipment must include:**
- Labeled disk/CD containing subject data.
- Completed DXA Transmittal Form (white copy) accompanying the subject data.

**Ship data to: 7707 Gateway Blvd, 3rd FL, Newark, CA 94560**

Please reference your SMART Portal user guide for instructions on how to submit data electronically.

## CONTACT INFORMATION

**Samumed SM04690-OA06 Team**
**Email:** MI_DEP_MSK.Team.SM04690-OA-06@bioclinica.com
**Fax**: +1 (503) 284-3357

**Instrument Quality Control Email :** IQC@bioclinica.com

**OFFICE HOURS :** Weekdays from 8:00am – 5:00pm **(Pacific Standard Time)**

## BIOGRAPHY EXAMPLE



## SUBJECT BIOGRAPHY ENTRY

**Update Attendant Initials, Visit ID, Height and Weight at follow-up visits.**

| | | |
|---|---|---|
| **Last Name:** | XXX6XXX | Enter 7-digit Subject ID number (3-digit site number-6 follow by 3-digit subject number) |
| **Patient ID:** | XXX6XXX | Enter 7-digit Subject ID number (3-digit site number-6 follow by 3-digit subject number) |
| **Operator:** | SCM | Enter initials of the technologist acquiring the scans |
| **DOB:** | MM-DD-YYYY | Enter the year of birth with day and month as 01-Jan |
| **Height:** | 165 | Enter to the nearest inch/ cm |
| **Weight:** | 59 | Enter to the nearest pound/kg |
| **Sex:** | F | Enter F for female or M for male |
| **Ethnicity:** | Asian | Enter Hologic code for ethnic group |

## DXA SCAN ACQUISITION MODES

| Anatomical Site | Delphi, Discovery, & Horizon | |
|---|---|---|
| Lumbar Spine | Array | **Scan modes can affect bone density data.** For consistency, use the modes listed here for your scanner model. If the image quality appearing while scanning a subject is not of good quality, stop the scan and check that the scan mode is appropriate; if necessary, try a different scan mode. **Maintain consistency at follow-up.** |
| Femur | Array | |

| **Do not use** Express, Quick View, Turbo, Fast or Survey modes. | **Ensure the System Configuration setting (Analyze tab) for auto analysis is disabled.** | ☑ Disable Auto Analysis |
|---|---|---|

## AVOIDING COMMON IMAGE ACQUISITION & DATA SUBMISSION ERRORS

- **Ensure** the subject demographic *and* visit details are entered correctly into the DXA software and DXA Transmittal Form.
- **Ensure** that DXA scans are copied to transfer media or uploaded to Web Submission.
- For data submitted via courier, **ensure** the DXA Transmittal Form is submitted with the transfer media.
- **Use** the correct scan mode and **remove** external artifacts from the scan field.
- **Internal Artifacts** - if present in the scan field, describe in the Comment section of the DXA Transmittal Form.

**Hologic Windows Operating System Users**
**Ensure this box is not checked at the time of copying DXA scans:**

☐ De-identify protected health information   [ Copy Scans ]   [ Close ]

## HOLOGIC BMD ELIGIBILITY CRITERIA
Subject must have an evaluable spine and bi-lateral femurs to be included in the study.

**FOR ALL PROCEDURES – ENSURE THE SUBJECT IS COMFORTABLE AND REMAINS STILL**

## LUMBAR SPINE

- **Position** the block under the lower legs to reduce lordosis.
- **Ensure** the spine is reasonably straight. **Reposition** subject if necessary.
- **Ensure** the spine is centered in the scan field.
  - If scoliosis exists, **start** the scan off-center so average of L1-L4 is centered in scan field.
- **Ensure** the scan begins at the level of mid-L5 and ends at mid-T12.
  - **Use** the repositioning tool to begin at the correct level.
  - If ribs are not apparent at the T12 level, **continue** acquisition to the middle of vertebra with visible ribs.
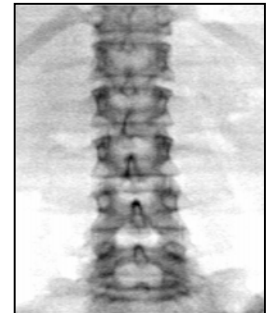


## FEMUR

- **Scan** left and right femur as indicated in the visit schedule.
- **Have** subject place hands on his/her chest. **Remove** shoes. **Center** subject on the scanner table. Place pillow under head if necessary.
- **Rotate** the entire leg to the positioning device. **Ensure** entire inner edge of foot rests against angled portion of positioning device.
- **Adjust** angle of the leg to obtain a vertically straight femoral shaft. It is usually necessary to abduct the leg.
- **Position** the femur correctly in scan field. **Use** repositioning tool to achieve consistent position of image in the scan field. **Allow** scan to end by default.
- If abnormalities appear when scanning the hip, **acquire** the other side to see if a better image is possible. Do not change sides at follow-up.



## DXA TRANSMITTAL FORM COMPLETION