The Bone Trial

Manual of Procedures (MOP)

Developed by:
The Clinical Research Computing Unit (CRCU)
University of Pennsylvania School of Medicine
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1. Study Summary

Title	The Testosterone Trial – The Bone Trial
Protocol Number	814217
Study Design	Randomized, placebo-controlled, double-blind study
Study Duration	5 Years
Study Centers	Nine clinical sites participating in the T Trial
Objectives	To test the hypothesis that testosterone treatment for one year will increase volumetric trabecular bone mineral density (vBMD) of the lumbar spine as measured by quantitative computed tomography (QCT) compared with placebo treatment
Number of Participants	200
Diagnosis and Main Inclusion Criteria	Participants in this study will be men enrolled in the T Trial, a randomized, placebo-controlled, double-blind study of seven coordinated trials in men >65 years of age, using AndroGel or placebo gel for one year. Men in the trial have unequivocally low testosterone concentration (average of 2 morning testosterone values, <275ng/dL), and symptoms and objective manifestations of mobility disability, low libido, or low vitality.
Study Product, Dose, Route, Regimen	AndroGel ® 1%, testosterone in an alcohol-water gel, administered transdermally in doses from 5 to 15 grams per day, adjusted as necessary to maintain the serum testosterone concentration within the range of normal for young men.
Duration of administration	AndroGel or placebo will be administered for one year.

2. Introduction

2.A. Study Overview

An important goal of the Bone Trial is to determine if testosterone treatment is associated with favorable changes in bone quality including:

- Increase in volumetric trabecular bone mineral density of the lumbar spine as measured by quantitative computed tomography (QCT)
- Increase in volumetric trabecular bone mineral density of the hip, as determined by QCT
- Increase in bone strength and strength-to-density ratio of the spine and hip, as determined by finite element analysis of the QCT data
- Increase in areal BMD of the lumbar spine and proximal hip, as measured by DXA

Subjects who are being screened for the Testosterone Trial will be invited to take part in the Bone Trial. Recruitment for the bone portion of the T Trial will take place at 9 of the 12 T Trial sites. Two hundred men will be recruited across the 9 sites.

Participation in the Bone Trial consists of four additional scans: the first two scans, a QCT and a DXA, each of the spine and the hip, will occur around the time of the baseline visit, prior to the start of gel use. The third and fourth scans, also a QCT and a DXA of both the spine and the hip, will occur at the end of the treatment phase around the time of the Month 12 visit. If feasible at the site, the QCT and DXA scans at each time point can occur on the same day.

*Please note: the DXA scan at baseline is needed to finalize eligibility in this trial; therefore it will be done any time after a subject has signed the study informed consent for this trial. Depending on the results of the DXA, the subject will be enrolled and proceed with the Baseline QCT scan.

2.B. Study Sites

The following 9 sites will recruit men for the bone sub study:

- Boston University, Boston, MA
- University of Alabama, Birmingham, AL
- University of California at Los Angeles, Los Angeles, CA
- University of California at San Diego, San Diego, CA
- University of Minnesota, Minneapolis, MN
- University of Pittsburgh, Pittsburgh, PA
- Yale University, New Haven, CT
- Baylor University, Houston, Texas
- Northwestern University, Chicago, Illinois

2.C. Data Coordinating Center

The University of Pennsylvania, School of Medicine, in Philadelphia, PA, serves as the administrative center for the research network. The Center for Clinical Epidemiology and Biostatistics and the Clinical Research Computing Unit (CRCU) function as the Data Coordinating Center (DCC) for the

study in providing comprehensive regulatory oversight, research management, tools and technology for this clinical trial.

2.D. Sponsors

The National Institute on Aging (NIA) and Abbott Laboratories, Abbott Park, Illinois, are the sponsors of the study.

2.E. FDA and IND Status

The Food and Drug Administration (FDA) will oversee the trial. It has been assigned Investigational New Drug (IND) # 104707.

3. Inclusion/Exclusion Criteria

Subjects who are being screened for the T Trial will be evaluated for eligibility for the Bone Trial.

3.A. Inclusion Criteria:

There will be no specific inclusion criteria for the Bone Trial. Participants will only be required to sign an informed consent form specifically for the Bone Trial.

3.B. Exclusion criteria:

T Trial participants who have the following conditions or take the following medications will not be eligible to participate in the Bone Trial:

- Bone mineral density by DXA at the lumbar spine, total hip or femoral neck lower than -3.0.*
- Elevated serum calcium (>10.5 mg/dL) at Screening Visit 1
- Medications that could influence bone, eg anticonvulsants**, glucocorticoids (prednisone >20 mg/d >2 wk/year), bisphosphonates (alendronate, risedronate, ibandronate), denosumab, and teriparatide. Calcium and OTC vitamin D supplements will be allowed
- Any procedure or condition that prevents QCT analysis of the lumbar vertebrae***

***Subjects who Have Lumbar Vertebrae That Cannot be Analyzed by DXA**

It may be the case that a subject's baseline DXA **spine** scan cannot be analyzed because there is not a sufficient area of lumbar vertebrae 1-4 available for analysis. This will not immediately exclude a subject since a QCT needs at most only one vertebra for analysis. However, in the case of a DXA spine scan that cannot be read, subjects should have at least one hip free of hardware at baseline so they may have a DXA reading of their hip for eligibility.

****Subjects Who Are Taking Anticonvulsants**

Not all anticonvulsants affect bone in the same way; therefore we will allow participants who are on the following anticonvulsants: gabapentin, valproic acid, lamotrigine, levetiracetam, pregabalin, tiagabine, and clonazepam. We will continue to exclude those on phenytoin, phenobarbital, carbamazepine, primadone, oxycarbazepine, and topiramate.

*****Definition of "Available for QCT Analysis"**

QCT scans of the spine are able to provide an analysis of as little as one vertebra. "Available for QCT analysis" will be defined as having at least one vertebra from vertebrae 1-4 available for analysis by QCT. In cases where site personnel are not sure if a subject has enough vertebrae for analysis, the site should email the DCC to confirm eligibility.

******Subjects Who Have Had Partial or Total Hip Replacement**

Please note that subjects with total arthroplasty, hemiarthroplasty or plates or screws in their hip will not be excluded from participating in this trial as they can still undergo the QCT of the spine. They will not, however, be able to undergo the QCT of the hip and this should be documented from enrollment through the end of the study. There is a space provided on the eligibility form (BONEELIG) to indicate if a subject can undergo a QCT of the hip. DXA should be performed on the good hip. In the rare case of double hip replacement, subjects will only undergo a DXA and QCT of the spine.

4. Informed Consent Administration and Visit Activities

4.A. Prescreening, Screening Visit 1 (SV1) and Screening Visit 2 (SV2)

Subjects will follow the procedures for Prescreening, SV1, & SV2 according to the protocol and manual of procedures for the main Testosterone Trial. Although subjects will not be able to undergo any bone trial related procedures until they are determined to be eligible for the main Testosterone Trial and are randomized to a study arm, they will be eligible to discuss and to consent to the Bone Trial as early as SV2**. Please note that once each of the main trials of the T Trial (Physical Function, Vitality, and Sexual Function) has met their enrollment goals, eligibility and participation in the Bone Trial or the CV Trial will be a requirement for the T Trial; therefore sites should start screening for the Bone Trial during the prescreening phone call. Informed Consent for the Bone Trial should then be attained at Screening Visit 1. A Bone Trial Screening form, which can be found at the end of this manual, can be used to screen subjects for the Bone Trial during the prescreening phone call and at SV1. When completing this screening form, please remember that subjects may still be eligible for the Bone Trial even if they have undergone the procedures in Question 2. It is important to document from the beginning any procedures that a subject may have had that could prevent analysis of the lumbar vertebrae. If sites need help deciding whether a subject with a history of surgery or a condition that affects the lumbar spine may proceed, they should contact the sponsor.**

4.B. Baseline DXA Scan of the Hip and Spine

This scan can be performed during the SV2 visit up to 2 weeks after the baseline T Trial study visit but prior to starting study gel application. Since the DXA measurement is needed to determine eligibility in the bone trial, and bone trial eligibility is now a requirement for the T Trial, all efforts should be made to have a subject undergo the Baseline DXA scan prior to randomization.

There are essentially 3 time points at which the DXA scan be performed and this will vary from site to site based on local decisions and consent forms. The DXA can be performed on all participants at

the SV2 visit or the DXA can be completed at SV2 for men who reported lower back surgery at their prescreening and/or SV1 visit. The DXA can be scheduled after eligibility has been assessed, via lab work, after the SV2 visit and before baseline. Lastly the DXA can be completed at the baseline visit before the randomization takes place. Please note if the participant's T score is between -2.7 and -3.0 the visit will need to be canceled and rescheduled until the scan is read by the DXA center. By performing the DXA at baseline sites do run the risk of bringing men in for baseline, performing the DXA, and then having to cancel the visit.

DXA scans will be scheduled according to the procedures in place at each site. Please see Section 5A on page 10 of this MOP for Site specific responsibilities for all DXA scans in this trial.

Once scheduled, site coordinators should call to remind subjects of their upcoming scan the day before the visit, and to make sure that they have not had any procedures requiring barium/ isotopes within the 7 days prior to the DXA scan. If they have had procedures involving barium/isotopes within the week prior to the DXA scan, they will need to be rescheduled. Participants should also be reminded to refrain from taking any vitamins or calcium supplements on the day of the DXA scan.

Each time a subject presents for a DXA scan for this trial they must be accompanied by 2 copies of the DXA Hologic Biological Form, which can be found at the end of this Manual and on the T Trial website. Coordinators must complete this form and make 2 copies. The original will be kept at the site and the 2 copies will be sent with the subject to the DXA center. Using this form, the DXA operator will create the Hologic Biography. DXA operators will not be able to scan subjects who do not have this form. DXA operators will be instructed to keep one copy of the Bone Hologic Form and to send the remaining copy along with the participant scan log to the DXA QA center each month. The contact information for the DXA QA center can be found in Section 5B on page 11 of this MOP.

During the DXA scan, subjects will be asked to lie down on an examination table while the scanner above the table moves over their lower body and measures the density of the lumbar spine and hip bone. A DXA gives a rough estimate of the risk of fracture.

The DXA scan takes about 30 minutes.

For more details of the DXA scan, specifically for the DXA operators, please refer to the DXA Operations Manual.

4.C. Enrollment

Once a subject has undergone the baseline DXA scan, their eligibility in the Bone Trial can be finalized. As previously stated, for subjects to be enrolled in the Bone Trial, they must have a bone mineral density by DXA at the lumbar spine, total hip or femoral neck ≥ -3.0. If the scan has a T-score of ≤ -2.8 at one of these sites, the low BMD/ EBL form should be completed and the scans should be sent to UCSF immediately for confirmation of accuracy in acquisition and analysis. Even if subjects have previously met all other eligibility criteria prior to this visit (i.e. serum calcium, medication review, etc.) but have a confirmed bone mineral density by DXA of less than -3.0, they will not be enrolled and will not proceed with any other Bone Trial procedures. For this reason, subjects should be scheduled for their DXA scan first, before the baseline QCT, as soon as possible after consenting

to the Bone Trial. Please see the DXA Bone Density Operations Manual for more details of confirmation of a T-score at baseline and at Month 12.

4.D. Baseline QCT Scan of the Hip and Spine

Like the DXA scan, this scan can also be performed at SV2 up to two weeks after the baseline T trial visit, prior to starting study gel. Since the DXA scan is needed for eligibility it is ideal for the DXA scan to be scheduled first, to then completely enroll the subject into the Bone Trial, and then to perform the QCT scan. This will also expose the subject to less additional radiation if they are found to be ineligible after the DXA scan.

The Study Coordinator will be responsible for scheduling Bone Trial participants for their scan according to the procedures that are in place at each site. A list of all site responsibilities can be found in Section 5C on page 11 of this MOP.

The following is a general overview of the study procedure during a QCT scan:

Patient Evaluation

At the visit, prior to the scan, subjects will be evaluated for:

- Verification of identity
- Patient weight above 300 pounds or above the manufacturer recommended limit for the scanner and table. Such patients should not be scanned to reduce potential injury from equipment malfunction.
- Ability to follow breath holding instructions.

Initiation of QCT Scan Form

At each baseline visit, a new QCT Scan Form should be initiated by filling in the Participant ID on a blank form. This form will then be stored for later use at the month 12 visit. At each one-year follow-up visit, the QCT Scan Form for the participant should be located and made available during the visit. This form can be found at the end of this MOP, as well as on the T Trial website.

Record Participant Demographics

Prior to scan acquisition, the subject's height (in cm) and weight (in kg) will be measured without shoes and in light clothing. Record this information on the QCT Scan Form along with the subject's age. If the subject is older than 89 years, record the age as "90 or older."

Completion of the QCT Scan Form

Just prior to scan acquisition, fill in the remaining fields of the QCT Scan Form. If this is a one-year follow-up visit, verify that CT scanner and table height are identical to those recorded during the baseline visit. All efforts should be made to acquire the follow-up scan on the same scanner used at baseline, even if the baseline scan had been acquired on a machine that was not the designated study scanner. If this cannot be done, indicate the reason in the Notes section. Any deviations from the baseline visit as noted by the CT Reading Center should also be included in the Notes sections such that those settings can be duplicated at the one-year visit.

QCT Scan Acquisition

The QCT scanner is a large, donut-like x-ray machine with a sliding table. For the QCT test, subjects will be asked to lie on their back in the QCT scanner with their arms above their head. The QCT scanner moves above the lower body, taking a series of X-ray pictures from different angles to create an image of the bones in the spine and hip.

The QCT scan will take about 30 minutes.

Please refer to the detailed information in section 6.2.5 of the CT Imaging Manual for specifics of the acquisition.

Verify Image Quality and Adherence to Protocol

Prior to transmitting scans to the CT Reading Center, the Head Technologist should review each scan for image artifacts (streaking or shading artifact, excessive noise) and for adherence to protocol (correct acquisition and reconstruction settings, complete coverage of bones of interest and the calibration phantom, patient motion). Although scans will not be repeated, the Head Technologist should remain aware of any issues that arise and make efforts to maintain high quality and to avoid repeating errors.

Transmit Data to CT Reading Center

The QCT Scan Form will be faxed to the CT Reading Center and the DICOM formatted QCT images will be transmitted electronically to the CT Reading Center.

For more details of the QCT scan, please refer to the QCT Scan Protocol and CT Imaging Manual.

4.E. Calcium and Vitamin D Treatment

Many older men have inadequate intake of calcium and vitamin D. Therefore, participation in the Bone Trial includes providing calcium and OTC vitamin D supplements to all men in the Bone Trial. It is likely that this supplementation will improve bone density in the treatment as well as the placebo group. As a result, the sample size estimation has been calculated based on a study that employed similar supplementation. Subjects will be reminded to take calcium and vitamin D at each study visit. The calcium and vitamin D are contained in one supplemental pill. Men taking supplements of calcium and Vitamin D outside of the study may continue to take their daily supplements and do not necessarily need to take the supplementation provided through the trial.

1. **Calcium**

   Subjects will be given a supply of calcium supplements and instructed to take 1200 mg of elemental calcium a day, which is the amount recommended by the NIH and the National Osteoporosis Foundation.

2. **Vitamin D**

   Subjects will be given a supply of OTC vitamin D and instructed to take 800 units of vitamin D a day.

4.F. Follow-up QCT Scans of the Hip and Spine

Subjects will undergo a second QCT scan at month 12 of the main Testosterone Trial following the same exact procedures as the baseline scan, except that no new QCT scan form will be generated, instead the baseline QCT scan form will be used.

4.G. Follow-up DXA Scans of the Hip and Spine

Subjects will undergo a second DXA scan at month 12 of the main Testosterone Trial following the same exact procedures as the baseline scan.

5. Site Responsibilities for Scanning

5.A. Site Responsibilities for DXA Scans

Sites must ensure the overall quality and completeness of the DXA data and that all protocols and procedures are strictly followed. Specific responsibilities include the following:

1. Require that operators are properly trained and certified. If there are state requirements for DXA operators, these must be met;
2. Identify a chief densitometry operator to train and supervise other operators;
3. Perform and review daily QC scans;
4. Assure that proper archiving and back-up procedures for participant scans are performed and that archives are stored securely on appropriate archiving media until the end of the study;
5. Once a month, send the following to the UCSF DXA QA Center
   a. All hip and spine scans acquired during the month
   b. Any reanalyzed scans from the previous month
   c. Log of participants scanned
   d. Low BMD / EBL forms, if appropriate
   e. All spine phantom scans
   f. Printouts of plots of the daily QC data for spine phantom (BMD, BMC, Area)
   g. Hologic service reports, if appropriate
6. Reanalyze centrally reviewed scans, as requested by the QA Center
7. Assure proper functioning of hardware/software and request service from Hologic:
   a. Notify Hologic and the QA Center of any machine or software problems or if the QDR machine is being relocated
   b. Record machine/software problems and service on the Hologic DXA Repair/Service/Upgrade Log
   c. Perform 10 QC spine phantom scans before (if possible) and after service
   d. Perform 10 QC spine phantom scans before and after machine relocation
8. Contact the DXA QA Center with any questions or problems that cannot be dealt with in the batch mailings.

5.B. DXA QA Center Contact Information

Caroline Navy
Bone Trial DXA Quality Assurance Center
University of California, San Francisco
185 Berry Street, Lobby 5, Suite 5700
San Francisco CA 94107-1762
Telephone: (415) 514-8096
Fax: (415) 514-8150
cnavy@psg.ucsf.edu

5.C. Site Responsibilities for QCT Scans

Each Imaging Center will assign personnel to the following roles: Study Coordinator, Head Technologist, QA Technologist, and CT Technologists. Note that one person may assume multiple roles. Specific responsibilities include:

Study Coordinator

- Act as the primary contact for the CT Reading Center and the Data Coordinating Center
- Ensure properly qualified personnel is assigned to study specific tasks
- Ensure training is disseminated in the event of turnover in study personnel
- Maintain proper documentation of study activities
- Inform OND and CRCU in advance if the study CT scanner must be changed
- Schedule patient visits
- Assign study IDs to study participants and maintain the re-identification key
- Monitor and ensure overall quality of study performance at the Imaging Center

Head Technologist

- Act as the primary contact for the CT Reading Center for technical issues directly related to scan acquisition
- Be familiar with and obtain proper training for study specific protocols
- Train other technologists who will participate in this study including those who join the study as a result of turnover in personnel
- Pre-program the CT scanner with the study scan protocols
- Perform or be present during acquisition of all patient scans, or ensure that a properly trained technologist that has read this manual is present at the time of acquisition in the event that the Head Technologist cannot be present
- Review images for quality and adherence to protocol before transmittal to the CT Reading Center
- Ensure proper de-identification of study data before transmittal to the CT Reading Center
- Manage transmission of study data to the CT Reading Center

QA Technologist

- Acquire cross-calibration phantom scans at study start and in the event of any scanner major scanner maintenance or upgrade
- Perform monthly QA scans using the study phantom

- Perform or monitor routine scanner quality checks and alert the Head Technologist and Study Coordinator to any deviations

All CT Technologists will be adequately trained in the acquisition of computed tomography scans, including adequate knowledge of the ALARA principles of radiation exposure. They must have appropriate knowledge of cross-sectional anatomy, physiology, and pathology related to the spine and hip. They must be certified as RTs in their state. It is recommended that technologists have at least two years of experience in computed tomography. The technologist should have basic knowledge of computer software applications, data formatting, and experience with the workstations and data formatting / transmission procedures related to CT image acquisition. Each technologist involved in the study should also have a complete understanding of the local CT protocol, and be experienced at providing breath-holding instruction.

At least one technologist who has read this manual and has appropriate training must be present during acquisition. If the primary technologist is absent, an alternate technologist with equivalent qualifications and familiarity of the manual may execute the protocol.

5.D. QCT Reading Center Contact Information

Any issues or questions that arise related to the imaging procedure should be directed to the CT Reading Center via email preferred, or by phone if immediate assistance is required. Requests for changes to study protocols should be made in writing via email or fax.

David Lee
ttrial@ondiagnostics.com
phone: 510-204-0688
fax: 510-356-4349

6. Bone Study Forms

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Bone Trial Screening** Pre-Screening & Screening Visit 1 (Completed by Research Coordinator)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

All responses to Question 1 must be "NO" in order for the participant to be eligible.

1. Participant is taking one of the following medications
   a. Anticonvulsants (Phenytoin, Phenobarbital, Carbamazepine, Primidone, Oxycarbazepine, and Topiramate) ❑$_1$ Yes ❑$_0$ No
   b. Glucocorticoids (prednisone >20 mg/day >2 week/year) ❑$_1$ Yes ❑$_0$ No
   c. Bisphosphonates [e.g., alendronate (Fosamax), risedronate (Actonel), ibandronate (Boniva), Zolandronate (Reclast, Zometa)], denosumab (Prolia), or teriparatide (Forteo)] ❑$_1$ Yes ❑$_0$ No

2. Has the participant had any procedure or condition wherein lumbar vertebrae 1-4 are not available for analysis (e.g. lumbar laminectomy, fusion, or metal in the lumbar area)? ❑$_1$ Yes ❑$_0$ No
   a. If YES, is the participant being excluded for this reason? ❑$_1$ Yes ❑$_0$ No

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Bone Trial Eligibility** Baseline (Completed by Research Coordinator)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Inclusion Criteria

The response to question 1 must be "YES" in order for the participant to be eligible.

1. Has the Bone Trial Informed Consent form been signed? ❑1 Yes ❑0 No
   a. If YES, what was the date of consent? __ __/__ __/__ __ __ __ (mm dd yyyy)

Exclusion Criteria

All responses to questions 2-4 must be "NO" in order for the participant to be eligible.

2. Participant has elevated serum calcium (>10.5 mg/dL) at Screening Visit 1? ❑1 Yes ❑0 No
3. Participant is taking one of the following medications
   a. Anticonvulsants ❑1 Yes ❑0 No
   b. Glucocorticoids (prednisone >20 mg/day >2 week/year) ❑1 Yes ❑0 No
   c. Bisphosphonates [e.g., alendronate (Fosamax), risedronate (Actonel), ibandronate (Boniva), Zolandronate (Reclast, Zometa), denosumab (Prolia), or teriparatide (Forteo)] ❑1 Yes ❑0 No
4. Has the participant had any procedure or condition wherein lumbar vertebrae 1-4 are not available for analysis (e.g. lumbar laminectomy, fusion, or metal in the lumbar area)? ❑1 Yes ❑0 No

4. Participant has had any of the following procedures:
   c. presence of plates or screws for hip fracture repair ❑1 Yes ❑0 No
   d. lumbar laminectomy ❑1 Yes ❑0 No
   e. metal in the lumbar area ❑1 Yes ❑0 No
   f. other procedure or condition wherein the 4 lumbar vertebrae are not available for analysis ❑1 Yes ❑0 No

5. Is participant eligible for the **Bone Trial** based on the inclusion and exclusion criteria? ❑1 Yes ❑0 No
6. Are there reasons other than eligibility that the clinical site excludes this participant from the Bone Trial? ❑1 Yes ❑0 No
7. Is participant eligible for QCT scan of the hip? ❑1 Yes ❑0 No

   If NO, has the participant had any of the following procedures:
   a. total hip arthroplasty ❑1 Yes ❑0 No
   b. hemiarthroplasty of the hip ❑1 Yes ❑0 No

   c. Please list any other reasons the participant is not eligible for QCT scan of the hip:

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Bone Trial Enrollment** Baseline (Completed by Research Coordinator)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Is the participant eligible based on the baseline DXA scan result? ❑$_1$ Yes ❑$_0$ No

   A participant is eligible when the bone mineral density at the lumbar spine, total hip or femoral neck t score is greater than or equal to -3.0 as reported by the UCSF Reading Center.

Answer question 2 when the baseline DXA results are confirmed by the Reading Center.

Based on the eligibility criteria and the DXA scan results, is the participant being enrolled in the Bone Trial? ❑$_1$ Yes ❑$_0$ No

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Bone Trial - Bone Scan** Baseline and Month 12 (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

DXA Scan

1. Have you had any of the following tests within the past 7 days:

a. Barium Enema	❑$_1$ Yes	❑$_0$ No
b. Upper GI X-ray series	❑$_1$ Yes	❑$_0$ No
c. Lower GI X-ray series	❑$_1$ Yes	❑$_0$ No
d. Nuclear medicine scan	❑$_1$ Yes	❑$_0$ No
e. Other tests using contrast (“dye”) or radioactive materials	❑$_1$ Yes	❑$_0$ No

For question 2, check N/A if participant is not eligible for a hip scan.

2. Was a hip scan performed? ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ N/A

If YES:

a. Date of hip scan __ __/__ __/__ __ __ __ (mm dd yyyy)

b. Which hip was scanned? ❑$_1$ Right ❑$_2$ Left

If NO:

a. Please specify reason:_____

3. Was a spine scan performed? ❑$_1$ Yes ❑$_0$ No

If YES:

a. Date of spine scan __ __/__ __/__ __ __ __ (mm dd yyyy)

If NO:

b. Please specify reason: _____

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Bone Trial - QCT Scan** Baseline and Month 12 (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

For question 2, check N/A if participant is not eligible for a hip scan.

1. Was a QCT scan of the hip performed? ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ N/A

If YES:

a. Date of scan __ __/__ __/__ __ __ __
mm dd yyyy

If NO:

b. Please specify reason:__

1. Was a QCT scan of the spine performed? ❑$_1$ Yes ❑$_0$ No

If YES:

a. Date of scan __ __/__ __/__ __ __ __
mm dd yyyy

If NO:

b. Please specify reason:__

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Bone Trial Completion** Visit __ __ (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Complete this form when the participant completes the study or terminates early.

1. Did the participant complete the study?

   ☐ 1 Yes

   ☐ 0 No If **NO**, date participation stopped? Date __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

2. Indicate the primary reason that participation in the Bone Trial has stopped:

   ☐ 1 Serious Adverse Event
   ☐ 2 Physician withdrew participant
   ☐ 3 Personal conflict
   ☐ 4 Participant no longer interested in participating
   ☐ 5 Death If **YES**, Date of Death __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

   ☐ 98 Other reason, please specify:

3. P.I. Signature: _____

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Bone Trial – Supplement Distribution Log** (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Line #	Name of Supplement	Visit	Date of Distribution	Lot #	Number of Bottles Dispensed	Dispensed By (initials)
1	Calcium + Vitamin D	Baseline				
2	Calcium + Vitamin D	Month 3				
3	Calcium + Vitamin D	Month 6				
4	Calcium + Vitamin D	Month 9				
5	Calcium + Vitamin D					
6	Calcium + Vitamin D					
7	Calcium + Vitamin D					
8	Calcium + Vitamin D					
9	Calcium + Vitamin D					
10	Calcium + Vitamin D					

**** Distribute 3 bottles at Baseline, Month 3, Month 6, and Month 9.**

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **DXA Hologic Biographical Form** Visit __ __ Administrative Form	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Instructions

Study Coordinator: Fill out form completely and make 2 copies. Keep original. Send 2 copies to DXA lab with participant.

DXA Operator: Create or modify Hologic Biography from this form. Do NOT scan participant if you do not receive this form for every visit. Keep one copy and send one copy with Participant Scan Log to DXA Reading Center.

1. Birth date: __ __/__ __/__ __ __ __
mm dd yyyy

1. Sex ❑1 Male ❑2 Female

Record answers to questions 3 and 4 from the Baseline or Month 12 **ANTH** form.

2. Weight to nearest pound: _____ lb.

OR

Weight to nearest kilogram: _____ kg

3. Height in two forms: ____ ft. and ____ in.

and all inches ____ in.

OR

____ cm.

Record answer to question 5 from the **DEMO** form.

4. Race:

- ☐ North American Indian/Alaskan Native
- ☐ Asian
- ☐ Black/African American
- ☐ Native Hawaiian/Other Pacific Islander
- ☐ White/Caucasian
- ☐ Other ____

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **QCT Scan Form** Visit __ __ Administrative Form	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Instructions to QCT Scan Technician:

Complete this form at baseline, save it for your files, and use the reference information when performing a scan at month 12.

	Baseline	12-Month
Date Scan Completed		
Technologist Initials		
CT Scanner ID/Name		
CT Scanner Make		
CT Scanner Model		
Table Height		

Notes: _____