Administration Information:

Start Time: ____:____ ☐1 AM ☐2 PM
HH MM

End Time: ____:____ ☐1 AM ☐2 PM
HH MM

Technician ID: __ __ __

Wake Forest QC Review:

Date Reviewed: ____/____/ __ ____ __
MM DD YYYY

Reviewer ID: __ __ __

"I would like to ask you a few questions that require concentration and memory. Some are a little bit more difficult than others. Some questions will be asked more than once."

1. When were you born? __ __/__ __/__ __ __ __
   MM DD YYYY

2. Where were you born?

   a. City/Town _____ ☐1 Answer Given ☐0 Can't Do/ Refused ☐9 Not Attempted/ Disabled

   b. State/ Country _____ ☐1 Answer Given ☐0 Can't Do/ Refused ☐9 Not Attempted/ Disabled

"I am going to say three words for you to remember. Repeat them after I have said all three words: "shirt", "brown", "honesty"." ***Do not repeat the words for the participant until after the first trial. The participant may give the words in any order. If there are errors on the first trial, repeat the items up to six times until they are learned.***

First Trial Only:

3. a. Shirt ☐1 Answer Given ☐0 Can't Do/ Refused ☐9 Not Att/ Disabled

   b. Brown ☐1 Answer Given ☐0 Can't Do/ Refused ☐9 Not Att/ Disabled

   c. Honesty ☐1 Answer Given ☐0 Can't Do/ Refused ☐9 Not Att/ Disabled

   d. Number of presentation necessary for the participant to repeat the sequence (1-7) _____

4 I would like you to count from 1 to 5.

☐1 Able to count forward

☐2 Unable to count forward - ***Say "1-2-3-4-5"***

a. Now I would like you to count backwards from 5 to 1. ***Record responses in the order given.***

__ __ __ __ __

5. Spell "world".

☐1 Able to spell

☐2 Unable to spell **"It's spelled W-O-R-L-D"**.

a. Now spell "world" backwards. ***Record the letter in the order given.***

__ __ __ __ __

6. "What three words did I ask you to remember earlier?"

The words may be repeated in any order. If the participant cannot give the correct answer after a category cue, provide the three choices listed. If the participant still cannot give the correct answer from the three choices, mark 0 and provide the correct answer.

a. Shirt

☐3 Spontaneous recall

☐2 Correct word/incorrect form

☐2 After **"Something to wear."**

☐1 After **"Was it shirt, shoes or socks?**

☐0 Unable to recall/refused (provide the correct answer)

☐9 Not attempted/disabled

b. Brown

☐3 Spontaneous recall
☐2 Correct word/incorrect form
☐2 After **"A color"**
☐1 After **"Was it blue, black, brown?**
☐0 Unable to recall/refused (provide the correct answer)
☐9 Not attempted/disabled

c. Honesty

☐3 Spontaneous recall
☐2 Correct word/incorrect form
☐2 After **"A good, personal quality."**
☐1 After **"Was it honesty, charity, modesty?**
☐0 Unable to recall/refused (provide the correct answer)
☐9 Not attempted/disabled

7. What is today's date? Probe for the month, day or year if not volunteered. ____/____/____ (MM/DD/YYYY)

a. What is the day of the week? _____ ☐1 Correct ☐0 Error/Refused ☐9 Not Attempted/ Disabled
Enter "X" if no response.

b. What season of the year is it? _____ ☐1 Correct ☐0 Error/Refused ☐9 Not Attempted/ Disabled
Enter "X" if no response.

8. What state are we in? _____ ☐1 Correct ☐0 Error/Refused ☐9 Not Attempted/ Disabled
Enter "X" if no response

a. What country are we in? _____ ☐1 Correct ☐0 Error/Refused ☐9 Not Attempted/ Disabled
Enter "X" if no response

b. What city/town are we in? _____ ☐1 Correct ☐0 Error/Refused ☐9 Not Attempted/ Disabled
Enter "X" if no response

c. "Are we in a clinic, store, or home?"

If the correct answer is not among the three alternatives, (e.g., hospital or nursing home), substitute it for the middle alternative (store). If the participant states that none is correct, ask them to make the best choice of the three options.

☐1 Correct ☐0 Error/Refused ☐9 Not Attempted/ Disabled

9. Point to the object or a part of your own body and ask the participant to name it. Score 0 if the participant cannot name it within 2 seconds or gives an incorrect name. Do not wait for the participant to mentally search for the name.

a. Pencil: "What is this?"	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled
b. Watch: "What is this?"	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled
c. Forehead: "What do you call this part of the face?"	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled
d. Chin: "…And this part?"	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled
e. Shoulder"…And this part of the body?"	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled
f. Elbow: "…And this part?"	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled
e. Knuckle: "…And this part of the hand?"	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled

10. **"**What animals have four legs? **"Tell me as many as you can."**

Discontinue after 30 seconds. Count all correct responses. If the participant gives no response in 10 seconds, and there are at least 10 seconds of remaining time, gently remind (once only) ***"What (other) animals have four legs?"*** *The first time an incorrect answer is provided, say* ***"I want four-legged animals."*** *Do not correct for subsequent errors.*

Score (total correct responses): _____

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

(Write any additional correct answers on a separate sheet of paper.)

11. "In what way are an arm and a leg alike?"

If the participant fails to give an answer that is worth 2 points, mark the appropriate score of 1 or 0. If the answer is not worth 2 points, coach the participant by saying *"An arm and a leg are both limbs or extremities."* ***Do not coach for questions 11a and 11b.***

☐$_2$ Limbs, extremities

☐$_1$ Lesser correct answer (e.g., body parts, both bend, have joints)

☐$_0$ Error (e.g., states differences, gives unrelated answer)/refused

☐$_9$ Not attempted/disabled

a. "In what way are laughing and crying alike?"

☐$_2$ Expressions of feelings, emotions

☐$_1$ Lesser correct answer (e.g. sounds, expressions)

☐$_0$ Error (e.g., states differences, gives unrelated answer)/refused

☐$_9$ Not attempted/disabled

b "In what way are eating and sleeping alike?"

☐$_2$ Necessary bodily functions, essential for life

☐$_1$ Lesser correct answer (e.g., bodily functions, relaxing, "good for you")

☐$_0$ Error (e.g., states differences, gives unrelated answer)/refused

☐$_9$ Not attempted/disabled

12. **"Repeat what I say: I would like to go out."**

Pronounce the individual words clearly, but with normal tempo of a spoken sentence.

☐$_2$ Correct

☐$_1$ 1 or 2 words missed

☐$_0$ 3 or more words missed/refused

☐$_9$ Not attempted/disabled

13. **"Now repeat: No ifs, ands or buts."**

Pronounce the Individual words clearly, but with normal tempo of a spoken sentence. Give no credit if the participant misses the "s".

a. no ifs	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled
b. ands	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled
c. or buts	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled

14. **Hold up Card 39-1 and say: "Please do this."**

If the participant does not close his eyes within 5 seconds, prompt by pointing to the sentence and saying, **"Read and do what this says."** If the participant has already read the sentence aloud spontaneously, simply say, **"Do what this says."**

Allow 5 seconds for the response. Mark 1 if the participant reads the sentence aloud, either spontaneously or after your request, but does not close her eyes. As soon as the participant closes her eyes, say **"Open."**

☐$_3$ Closes eyes without prompting

☐$_2$ Closes eyes after prompting

☐$_1$ Reads aloud, but does not close eyes

☐$_0$ Does not read aloud or close eyes/refused

☐$_9$ Not attempted/disabled

15. **"Please write the following sentence: I would like to go out."**

Hand the participant a piece of blank paper and a #2 pencil with eraser. If necessary, repeat the sentence word by word as the participant writes. Allow a maximum of 1 minute after the first reading of the sentence for the scored response.

Either printing or cursive writing is allowed. Assign 1 point for each correct word, but no credit for "I". For each word, mark 0 if there are spelling errors or incorrect mixed capitalization's (all letters printed in uppercase is permissible). Do not penalize self-corrected errors.

a. Would	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled
b. Like	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled
c. To	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled
d. Go	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled
e. Out	☐$_1$ Correct	☐$_0$ Error/Refused	☐$_9$ Not Attempted/ Disabled

f. ***Note which hand the participant uses to write. If this is not done, ask participant if she is right or left-handed.*** (For use in Question 17):

☐$_1$ Right

☐$_2$ Left

☐$_9$ unknown

16. **"Here is a drawing. Please copy the drawing onto this piece of paper."**

Hand the participant a piece of paper and Card 39-2. For right-handed participants, present the sample on their left side. For left-handed participants, present the sample on their right side. Allow one minute for copying. In scoring, do not penalize for self-corrected errors, tremors, minor gaps, or overshoots.

a. **Pentagon 1**

☐$_4$ 5 approximately equal sides

☐$_3$ 5 sides, but longest: shortest side is > 2:1

☐$_2$ Nonpentagon enclosed figure

☐$_1$ 2 or more lines, not an enclosure

☐$_0$ Less than 2 lines/refused

☐$_9$ Not attempted/disabled

b. **Pentagon 2**

☐$_4$ 5 approximately equal sides

☐$_3$ 5 sides, but longest: shortest side is > 2:1

☐$_2$ Nonpentagon enclosed figure

☐$_1$ 2 or more lines, not an enclosure

☐$_0$ Less than 2 lines/refused

☐$_9$ Not attempted/disabled

c. **Intersection**

☐2 4-cornered enclosure

☐1 Other than 4-cornered enclosure

☐0 No enclosure/refused

☐9 Not attempted/disabled

17 Refer back to Question 15f. to determine the participant's dominant hand. Hold up a piece of white paper in plain view of the participant but out of her reach, and say:

"Take this paper with your left (right for left-handed person) hand, fold it in half, and hand it back to me."

After saying the whole command, hold the paper within reach of the participant. Do not repeat any part of the command. Do not give visual cues for her to take or return the paper. She may hand it back with either hand.

a. Takes paper in correct hand	☐1 Correct	☐0 Error/Refused	☐9 Not Attempted/ Disabled
b. folds paper in half	☐1 Correct	☐0 Error/Refused	☐9 Not Attempted/ Disabled
c. Hands paper back	☐1 Correct	☐0 Error/Refused	☐9 Not Attempted/ Disabled

18. What three words did I ask you to remember earlier?"

The words may be repeated in any order. Administer even if the score = 0 on question 5. If the participant cannot give the correct answer after a category cue, provide the three choices listed. If the participant still cannot give the correct answer from the three choices, mark "0" and provide the correct answer.

a. **Shirt**

☐3 Spontaneous recall

☐2 Correct word/incorrect form

☐2 After **"Something to wear."**

☐1 After **"Was it shirt, shoes or socks?**

☐0 Unable to recall/refused (provide the correct answer)

☐9 Not attempted/disabled

b. **Brown**

☐3 Spontaneous recall

☐2 Correct word/incorrect form

☐2 After **A color."**

☐1 After **"Was it blue, black, brown?"**

☐0 Unable to recall/refused (provide the correct answer)

☐9 Not attempted/disabled

c. **Honesty**

☐3 Spontaneous recall

☐2 Correct word/incorrect form

☐2 After **A good personal quality."**

☐1 After **"Was it honesty, charity. modesty?"**

☐0 Unable to recall/refused (provide the correct answer)

☐9 Not attempted/disabled

19. **Special Problems?** ☐1 Yes ☐0 No

☐1 Vision

☐2 Hearing

☐3 Inability to write due to injury/illness

☐4 Illteracy/Lack of education

☐5 Language (difficulty speaking/understanding English

☐8 Other, specify_____

a. Secondary Problem ☐1 Yes ☐0 No

Specify:_____

THE T TRIAL — THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Adverse Event** (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials: __ __ __ Site: __ __

AE Sequence Number	Adverse Event Name	Grade	Was Event Serious? No Yes	Serious Event Type	Relationship to Study Drugs	Is this related to a Pre-Existing Condition? No Yes	Start Date (MMDDYYYY)	Stop Date (MMDDYYYY)	CV Event? No Yes
			☐ ☐			☐ ☐	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Continuing	☐ ☐
			☐ ☐			☐ ☐	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Continuing	☐ ☐
			☐ ☐			☐ ☐	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Continuing	☐ ☐
			☐ ☐			☐ ☐	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Continuing	☐ ☐
			☐ ☐			☐ ☐	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Continuing	☐ ☐
			☐ ☐			☐ ☐	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Continuing	☐ ☐
			☐ ☐			☐ ☐	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Continuing	☐ ☐

Grade	Serious Event Type	Relationship to Study Drug
1. Mild 2. Moderate 3. Severe 4. Life-threatening or Disabling 5. Death	1. None 2. Congenital Anomaly 3. Hospitalization 4. Disability 5. Important Medical Event 6. Life Threatening 7. Death	1. Not Related 2. Possibly Related 3. Definitely Related

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

1. What is the participant's current weight? __ __ __ . __ kg

2. What is the participant's current height? __ __ __ . __ cm ☐99 Required at SV2 and Month 12 visit.

3. What is the current BMI? _____ . _____ ☐99 Not required after SV2
   (Calculated by DMS.)

4. What is the participant's Blood Pressure? Reading 1:__ __ __ sys / __ __ __ dia __ __ __ heart rate (beats/min.)

   Reading 2:__ __ __ sys / __ __ __ dia __ __ __ heart rate (beats/min.)

   Participant is ineligible if systolic blood pressure >160 mm Hg or diastolic blood pressure >100 mm Hg.

   4a. Average blood pressure? _____ sys / _____ dia
   (Calculated by DMS.)

5. What is the participant's Waist Circumference? __ __ __ . __ cm

6. What is the participant's Hip Circumference? __ __ __ . __ cm

Repeat Blood Pressure Measurements

This section is used only when participants require a retesting of blood pressure due to suspension of blood pressure medication during the first set of measurements.

Date of Repeat Blood Pressure Measurements: __ __/__ __/__ __ __ __

7. What is the participant's Blood Pressure? Reading 1:__ __ __ sys / __ __ __ dia __ __ __ heart rate (beats/min.)

   Reading 2:__ __ __ sys / __ __ __ dia __ __ __ heart rate (beats/min.)

   Average blood pressure? _____ sys / _____ dia
   (Calculated by DMS.)

1. **Cancer Presence, Location and Amount (Complete 1a. – 1j):**

1a. **Prostate, right base, needle core biopsy:**

☐1 Adenocarcinoma (conventional, not otherwise specified)
☐2 No carcinoma, no high-grade PIN
☐3 No definitive features of androgen deprivation
☐98 Other (specify): _____

TUMOR EXTENT: ☐99 Not Applicable for this core

__ __ __ cm of one __ __ __ cm long biopsy
__ __ __ cm of a second __ __ __ cm long biopsy

1b. **Prostate, right mid, needle core biopsy:**

☐1 Adenocarcinoma (conventional, not otherwise specified)
☐2 No carcinoma, no high-grade PIN
☐3 No definitive features of androgen deprivation
☐98 Other (specify): _____

TUMOR EXTENT: ☐99 Not Applicable for this core

__ __ __ cm of one __ __ __ cm long biopsy
__ __ __ cm of a second __ __ __ cm long biopsy

1c. **Prostate, right apex, needle core biopsy:**

☐1 Adenocarcinoma (conventional, not otherwise specified)
☐2 No carcinoma, no high-grade PIN
☐3 No definitive features of androgen deprivation
☐98 Other (specify): _____

TUMOR EXTENT: ☐99 Not Applicable for this core

__ __ __ cm of one __ __ __ cm long biopsy
__ __ __ cm of a second __ __ __ cm long biopsy

1d. **Prostate, left base, needle core biopsy:**

☐1 Adenocarcinoma (conventional, not otherwise specified)
☐2 No carcinoma, no high-grade PIN
☐3 No definitive features of androgen deprivation
☐98 Other (specify): _____

TUMOR EXTENT: ☐99 Not Applicable for this core

__ __ __ cm of one __ __ __ cm long biopsy
__ __ __ cm of a second __ __ __ cm long biopsy

1e. **Prostate, left mid, needle core biopsy:**

☐1 Adenocarcinoma (conventional, not otherwise specified)
☐2 No carcinoma, no high-grade PIN
☐3 No definitive features of androgen deprivation
☐98 Other (specify): _____

TUMOR EXTENT: ☐99 Not Applicable for this core

__ __ __ cm of one __ __ __ cm long biopsy
__ __ __ cm of a second __ __ __ cm long biopsy

1f. **Prostate, left apex, needle core biopsy:**

☐1 Adenocarcinoma (conventional, not otherwise specified)
☐2 No carcinoma, no high-grade PIN
☐3 No definitive features of androgen deprivation
☐98 Other (specify): _____

TUMOR EXTENT: ☐99 Not Applicable for this core

__ __ __ cm of one __ __ __ cm long biopsy
__ __ __ cm of a second __ __ __ cm long biopsy

1g. **Prostate, left transition zone, needle core biopsy:**

☐1 Adenocarcinoma (conventional, not otherwise specified)
☐2 No carcinoma, no high-grade PIN
☐3 No definitive features of androgen deprivation
☐98 Other (specify): _____

TUMOR EXTENT: ☐99 Not Applicable for this core

__ __ __ cm of one __ __ __ cm long biopsy
__ __ __ cm of a second __ __ __ cm long biopsy

1h. **Prostate, right transition zone, needle core biopsy:**

☐1 Adenocarcinoma (conventional, not otherwise specified)
☐2 No carcinoma, no high-grade PIN
☐3 No definitive features of androgen deprivation
☐98 Other (specify): _____

TUMOR EXTENT: ☐99 Not Applicable for this core

__ __ __ cm of one __ __ __ cm long biopsy
__ __ __ cm of a second __ __ __ cm long biopsy

1i. **Prostate, _____, needle core biopsy:**

☐1 Adenocarcinoma (conventional, not otherwise specified)
☐2 No carcinoma, no high-grade PIN
☐3 No definitive features of androgen deprivation
☐98 Other (specify): _____

TUMOR EXTENT: ☐99 Not Applicable for this core

__ __ __ cm of one __ __ __ cm long biopsy
__ __ __ cm of a second __ __ __ cm long biopsy

1j. **Prostate, _____, needle core biopsy:**

☐1 Adenocarcinoma (conventional, not otherwise specified)
☐2 No carcinoma, no high-grade PIN
☐3 No definitive features of androgen deprivation
☐98 Other (specify): _____

TUMOR EXTENT: ☐99 Not Applicable for this core

__ __ __ cm of one __ __ __ cm long biopsy
__ __ __ cm of a second __ __ __ cm long biopsy

2. **Histologic Grade – Gleason Pattern**:
(if 3 patterns are present, record the most predominant and second most common patterns)

Primary Pattern:	*Secondary Pattern:*	*Tertiary Pattern:*
☐1 Grade 1	☐1 Grade 1	☐3 Grade 3
☐2 Grade 2	☐2 Grade 2	☐4 Grade 4
☐3 Grade 3	☐3 Grade 3	☐5 Grade 5
☐4 Grade 4	☐4 Grade 4	__ __ __ Estimate of percentage of the tumor that is a tertiary pattern
☐5 Grade 5	☐5 Grade 5	

Total Gleason Score: __ __ __

Cores involved by cancer: __ __ of __ __

3. **Extraprostatic extension:** (check all that apply) ☐1 Absent ☐2 Present in cores __ __ __

4. **Perineural invasion:** ☐1 Absent ☐2 Present

5. **Angiolympatic invasion (V):** ☐1 Absent ☐2 Present

6. **Additional Pathologic Findings (Check all that apply):**

- ☐ None identified
- ☐ High-grade prostatic intraepithelial neoplasia (PIN)
- ☐ Benign glands: Definitive features of androgen deprivation (check those that apply):
  - ☐ Basal cell hyperplasia
  - ☐ Inconspicuous glands
  - ☐ Marked atrophy (features overlap with non-AD simple atrophy)
  - ☐ Other (specify): _____
- ☐ Cancer glands: Definitive features of androgen deprivation (check those that apply):
  - ☐ Marked cytoplasmic vacuolization
  - ☐ Inconspicuous tumor cells
  - ☐ Other (specify): _____
- ☐ Inflamation (mononuclear only; criteria detailed in PMID 10569559)
  - ☐ Glandular
  - ☐ Periglandular (do not indicate if mild)
    - ☐ Moderate
      - ☐ Focal
      - ☐ Multifocal
      - ☐ Diffuse
    - ☐ Severe
      - ☐ Focal
      - ☐ Multifocal
      - ☐ Diffuse
  - ☐ Stomal (do not indicate if mild)
    - ☐ Moderate
      - ☐ Focal
      - ☐ Multifocal
      - ☐ Diffuse
    - ☐ Severe
      - ☐ Focal
      - ☐ Multifocal
      - ☐ Diffuse
- ☐ Other (specify): _____

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** **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 (phenytoin, phenobarbital, carbamazepine, primadone, oxycarbazepine, 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
4. Has the participant had any procedure or condition that prevents QCT analysis of the lumbar vertebrae? ❑1 Yes ❑0 No

Archived Questions

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.

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

DXA Scan

1. Have you had any of the following tests within the past 30 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

2. Was a hip scan performed? ❑1 Yes ❑0 No
   If YES:
   a. Date of hip scan __ __/__ __/__ __ __ __ (mm dd yyyy)
   b. Which hip was scanned? ❑1 Right ❑2 Left

3. Was a spine scan performed? ❑1 Yes ❑0 No
   If YES:
   a. Date of spine scan __ __/__ __/__ __ __ __ (mm dd yyyy)

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 must be "NO" in order for the participant to be eligible.

1. Participant is taking one of the following medications
   a. Anticonvulsants (Phenytoin, Phenobarbital, Primidone, please see MOP page 6 for full list) ❑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

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** **Benton Visual Recall Test** Visit __ __ (Quality Control Staff Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Design	Score for Figure A	Score for Figure B	Score for Figure C	Additional Errors for Designs *(If there are no additional errors place a "0" on the line.*
1	☐ 0 ☐ 0.5 ☐ 1			___
2	☐ 0 ☐ 0.5 ☐ 1			___
3	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	___
4	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	___
5	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	___
6	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	___
7	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	___
8	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	___
9	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	___
10	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	☐ 0 ☐ 0.5 ☐ 1	___

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** CARD Rotations Visit __ __ (Participant Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Card 1	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D
Card 2	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D
Card 3	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D
Card 4	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D
Card 5	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D
Card 6	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D
Card 7	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D
Card 8	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D
Card 9	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D
Card 10	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D	☐1 S ☐2 D

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Concomitant Medication**	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __

Seq. #	CMED #	Medication Name	Medication Class	Dose per Administration	Unit	Freq.	Route of Admin.	Start Date	Stop Date
			Note: This field is derived by the Data Management System to identify exclusionary medications					Note: Enter best estimate of medication start date. If month or day of start date is estimated, enter 01 for month or day. mm/dd/yyyy	Note: Enter best estimate of medication stop date. If month or day of stop date is estimated, enter 01 for month or day. mm/dd/yyyy
				☐ UNK				__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Continuing
				☐ UNK				__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Continuing
				☐ UNK				__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Continuing
				☐ UNK				__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Continuing
				☐ UNK				__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Continuing
				☐ UNK				__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Continuing
				☐ UNK				__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __ ☐ Continuing

Unit		Frequency	Route of Administration	
1 = tablespoon	10 = microcurie (mcc)	1 = 1X per day (qd)	1 = S.C. - subcutaneous	10 = nasal
2 = teaspoon	11 = grain	2 = 2X per day (bid)	2 = I.V. - intravenous	11 = sublingual
3 = ounce	12 = units	3 = 3X per day (tid)	3 = eye drops	12 = intravitreal
4 = gram	88 = unknown unit	4 = 4X per day (qid)	4 = I.M. - intramuscular	13 = peribulbar
5 = milligram (mg)	98 = other	5 = as needed (PRN)	5 = P.O. - by mouth	14 = intra-articular
6 = microgram (mcg)		88 = unknown	6 = P.R. - by rectum	15 = transdermal
7 = milliliter (ml)		98 = other	7 = topical	16 = by ear
8 = microliter (mcl)			8 = vaginal	88 = unknown
9 = millicure (mlc)			9 = oral inhalation	98 = other

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** Summary of Cognitive Function Tests (Research Coordinator Completed) Visit __ __	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

In the table below, please document whether or not a test was given. If a test was not given, please record the reason. Provide additional notes as needed at the bottom of the page.

Test Given			**Test Not Given Because….**			
	YES	NO	Physical Reason (specify below)	Not Cooperative (specify below)	Suspected Cognitive Impairment (specify below)	Other (specify below)
Wechsler Memory Scale Immediate Recall	☐	☐				
Trail Making Test Part A	☐	☐				
Trial Making Test Part B	☐	☐				
Benton Visual Retention Test	☐	☐				
Card Rotations	☐	☐				
Wechsler Memory Scale Delayed Recall	☐	☐				

Additional Notes:

Administration Information:

Participant's Randomized Version:	☐$_1$ A, B, C	☐$_2$ B, C, A	☐$_3$ C, A, B
Form Packet for this Visit:	☐$_1$ A	☐$_2$ B	☐$_3$ C
Start Time:	____:____ HH MM	☐$_1$ AM	☐$_2$ PM
End Time:	____:____ HH MM	☐$_1$ AM	☐$_2$ PM
Technician ID:	__ __ __		

Wake Forest QC Review:

Date Reviewed:	____/____/ __ ____ __ MM DD YYYY
Reviewer ID:	__ __ __

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

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

Section A. STUDY STOP

1. Did the participant complete the study, up to 24-months?

   ☐1 Yes If **YES**, Stop completing form

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

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

   ☐1 Serious Adverse Event
   ☐2 Lack of perceived efficacy by participant
   ☐3 Personal conflict
   ☐4 Participant no longer interested in participating
   ☐5 Death If **YES**, Date of Death _____ / _____ / __ _____ __
   MM DD YYYY
   ☐6 Participant withdraws post-treatment phase (12 months) **[Complete Section D]**
   ☐98 Other reason, please specify: _____

3. P.I. Signature: _____

Section B. TREATMENT STOP 1

4. Did the participant stop his study treatment prior to completing the treatment phase?

   ☐1 Yes If **YES**, proceed to the next question
   ☐0 No If **NO**, proceed to page 2 and answer section D

5. Date the participant stopped using his study medication: _____ / _____ / _____ __ __
   MM DD YYYY

6. Indicate the primary reason that the treatment was stopped:

   ☐1 Participant was diagnosed with Prostate Cancer
   ☐2 Participant's hemoglobin is > 17.5 g/dL and no cause of secondary erythocytosis was found
   ☐3 Participant began using a contraindicated medication (see EXMED for reference)
   Medication Name: _____
   Sequence number as recorded on CMED: __ __ __
   ☐4 Adverse Event or Serious Adverse Event
   Sequence number as recorded on AE: __ __ __
   ☐5 Participant has been non-compliant with his treatment
   ☐6 Participant has had 2 consecutive dose reductions and requires a 3rd
   ☐7 Participant's dose reduced to 0
   ☐98 Other reason, please specify: _____

7. Did the participant restart his medication? ☐1 Yes ☐0 No

   If **YES, w**hen? Date _____ / _____ / __ _____ __
   MM DD YYYY

If the participant stops treatment a second time, complete the next section; otherwise, proceed to section D.

Section C. TREATMENT STOP 2

8. Date the participant stopped using his study medication a second time: _____ / ____ / _____ — —
MM DD YYYY

9. Indicate the primary reason that the treatment was stopped for the second time:

- ☐ 1 Participant was diagnosed with Prostate Cancer
- ☐ 2 Participant's hemoglobin is > 17.5 g/dL and no cause of secondary erythocytosis was found
- ☐ 3 Participant began using a contraindicated medication (see EXMED for reference)
  Medication Name: _____
  Sequence number as recorded on CMED: __ __ __
- ☐ 4 Adverse Event or Serious Adverse Event
  Sequence number as recorded on AE: __ __ __
- ☐ 5 Participant has been non-compliant with his treatment
- ☐ 6 Participant has had 2 consecutive dose reductions and requires a 3rd
- ☐ 7 Participant's dose reduced to 0
- ☐ 98 Other reason, please specify: _____

Section D. Treatment vs. Placebo

Instructions: The following questions relate to the participant's opinion and the study staff's opinion on the drug course used in the TTrial **and must be completed at the Month 12 Visit or when participation stops.**

10. Does the participant think he has been taking testosterone or placebo?

- ☐ 1 Confident he is taking Testosterone
- ☐ 2 Somewhat sure he is taking Testosterone
- ☐ 3 Unsure if he is taking Testosterone or Placebo
- ☐ 4 Somewhat sure he is taking Placebo
- ☐ 5 Confident he is taking Placebo

11. Do you think the participant has been taking testosterone or placebo?

- ☐ 1 Confident he is taking Testosterone
- ☐ 2 Somewhat sure he is taking Testosterone
- ☐ 3 Unsure if he is taking Testosterone or Placebo
- ☐ 4 Somewhat sure he is taking Placebo
- ☐ 5 Confident he is taking Placebo

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

1. Has the CT Scan been performed? ❑1 Yes ❑0 No

   a. If YES, what was the date of the CT Scan? __ __/__ __/__ __ __ __ (mm dd yyyy)

   The following questions pertain to the Month 12 Visit Only.

   b. If YES, was a CT scan with contrast performed? ❑1 Yes ❑0 No

   c. If a CT scan with contrast was not performed, what was the reason?

      ❑1 Participant became allergic to contrast dye since baseline

      ❑2 Results of eGFR indicate the participant has developed renal insufficiency.

      ❑88 Other, specify: _____

2. Has Creatinine (and BUN, if required at your site) been done within 30 days of scan? ❑1 Yes ❑0 No

   a. If YES, were the results in the normal range? ❑1 Yes ❑0 No

3. Date of phone call to participant to initiate gel use? __ __/__ __/__ __ __ __ (mm dd yyyy)

Check the following boxes during the Baseline Visit ONLY, when applicable:

❑1 Participant instructed to begin gel application

❑1 DOSE log updated with date of FIRST gel application

Check the following box during the Month 12 Visit ONLY, when applicable:

❑1 DOSE log updated with date of LAST gel application

THE T TRIAL
THE TESTOSTERONE TRIAL

TESTOSTERONE TRIAL

Event Classification Form

PID: __ __ __ __ __ __
Site: __ __
Date: __ __/__ __/ __ __ __ __

1. Reviewed by: ❑1 Kasner ❑2 Messe ❑98 Other _____

2. Date event reviewed: __ __ / __ __ / __ __ __ __ (***mm/dd/yyyy***)

3. AE#: _____

Please base your review on the documentation provided from this investigation.

4. Was this a cerebrovascular event? ❑1 Yes ❑0 No (**STOP**)
   If yes:

   a. According to the TTRIAL outcome definitions, was this event (***select only one***)
   - ❑1 Intraparenchymal hemorrhage (**IPH**)?
   - ❑2 Subarachnoid hemorrhage (**SAH**)?
   - ❑3 Large-vessel cerebral infarction (**LVCI**)?
   - ❑4 Cardioembolic cerebral infarction (**CCI**)?
   - ❑5 Small-vessel cerebral infarction (**SVCI**)?
   - ❑6 Cerebral infarction not otherwise specified (**CINOS**)?

   b. Categorize probability for the Cerebrovascular event.
   - ❑1 Definite ❑2 Probable
   - ❑88 Cannot Determine

5. Was there a **second** cerebrovascular event during this hospitalization? ❑1 Yes ❑0 No (**STOP**)
   If yes:

   a. According to the TTRIAL outcome definitions, was this event (***select only one***)
   - ❑1 Intraparenchymal hemorrhage (**IPH**)
   - ❑2 Subarachnoid hemorrhage (**SAH**)?
   - ❑3 Large-vessel cerebral infarction (**LVCI**)?
   - ❑4 Cardioembolic cerebral infarction (**CCI**)?
   - ❑5 Small-vessel cerebral infarction (**SVCI**)?
   - ❑6 Cerebral infarction not otherwise specified (**CINOS**)?

   b. Categorize probability for the Cerebrovascular event.
   - ❑1 Definite ❑2 Probable
   - ❑88 Cannot Determine

Comments:

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Cardiovascular Eligibility** Baseline and Month 12 (Completed by Research Coordinator)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Inclusion Criteria

All responses to questions 1-2 must be "YES" in order for the participant to be eligible.

1. Has the CV Informed Consent form been signed? ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ N/A
   Check N/A at Month 12

   a. If YES, what was the date of consent? __ __/__ __/__ __ __ __ (mm dd yyyy)

2. Is the participant's eGFR greater than 60ml/min/1.73m^2? ❑$_1$ Yes ❑$_0$ No
   NOTE: Check estimated glomerular filtration (eGFR) as reported on the Quest lab report at SV1 or Month 12.

Exclusion Criteria

All responses to questions 3-10 must be "NO" in order for the participant to be eligible.

Ask the following questions to the participant:

3. Do you have an allergy to iodinated contrast medium? ❑$_1$ Yes ❑$_0$ No

4. Are you unable to hold your breath for 10 seconds? ❑$_1$ Yes ❑$_0$ No

5. Has a doctor or health care provider ever told you that you have a problem or irregularity with your heart rhythm such as tachycardia (a heart rate that is too fast), or other rhythm problems called atrial fibrillation or ventricular tachycardia? ❑$_1$ Yes ❑$_0$ No

For the following exclusion criteria question, refer to **ANTH** to determine the response.

6. Is the participant's weight more than 300 pounds? ❑$_1$ Yes ❑$_0$ No

For the following exclusion criteria questions, refer to **CVHX** at Baseline or **CVEVENTS** at Month 12 Visit and transcribe the responses:

7. Has the participant ever had a heart attack? ❑$_1$ Yes ❑$_0$ No

8. Has the participant ever had a stroke? ❑$_1$ Yes ❑$_0$ No

9. Has the participant ever had a procedure to open up blood vessels in the heart, such as a coronary stent or coronary artery bypass graft? ❑$_1$ Yes ❑$_0$ No

Question 10 -- Yale University ONLY

10. Does the participant currently use a pacemaker or defibrillator? ❑$_1$ Yes ❑$_0$ No

11. Is participant eligible for the **Cardiovascular Sub-study** based on the inclusion and exclusion criteria? ❑$_1$ Yes ❑$_0$ No

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Cardiovascular Event Questionnaire** Visit __ __ (Completed as Research Coordinator/Participant Interview)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. **Since the last T Trial study contact**, has a ***doctor*** or ***healthcare*** provider told you that you had:

a.	a heart attack?	❑1 Yes	❑0 No
b.	a stroke or mini-stroke?	❑1 Yes	❑0 No
c.	atrial fibrillation?	❑1 Yes	❑0 No
d.	vascular (arterial) disease in the legs?	❑1 Yes	❑0 No
e.	angina?	❑1 Yes	❑0 No
f.	heart failure?	❑1 Yes	❑0 No

If ***YES*** to any of the above, and NOT associated with a hospitalization below, collect additional HCP information on the CVADMIN form.

2. Have you been ***hospitalized***, ***including an Emergency Department (ED) visit***, for any of the following medical problems since the last T Trial study contact?

			If YES, # of Hospitalizations / ED visits
a.	Heart attack or suspected heart attack (also called acute myocardial infarction or MI)?	❑1 Yes ❑0 No	___ ___ ___
b.	Chest pain due to heart disease, angina, unstable angina, or angina pectoris?	❑1 Yes ❑0 No	___ ___ ___
c.	Heart failure or congestive heart failure?	❑1 Yes ❑0 No	___ ___ ___
d.	Heart surgery to improve the circulation of the heart, coronary artery by-pass surgery, CABG; or percutaneous angioplasty, with or without a stent?	❑1 Yes ❑0 No	___ ___ ___
e.	Abnormal heart rhythm or heart arrhythmia?	❑1 Yes ❑0 No	___ ___ ___
f.	Stroke, mini-stroke or brain attack, transient ischemic attack (TIA), bleeding in the brain, hemorrhagic stroke, or intracranial hemorrhage?	❑1 Yes ❑0 No	___ ___ ___
g.	Blockage in blood vessels in your neck (carotid artery disease)?	❑1 Yes ❑0 No	___ ___ ___
h.	Blockage in blood vessels in your legs, or peripheral artery disease?	❑1 Yes ❑0 No	___ ___ ___
i.	Blood clots in the legs, deep venous thrombosis?	❑1 Yes ❑0 No	___ ___ ___
j.	***RC determines:*** If ***YES*** in 2a-2i, how many ***separate*** hospitalizations/ED visits since last T Trial study contact?		___ ___ ___

If any hospitalizations occurred, collect additional information on the CVADMIN form.

3. Have you had any of the following ***tests or procedures*** since the last T Trial study contact?

			If *YES*, was the procedure/test.....	
a.	Echocardiography (also called ultrasound of the heart)?	❑$_1$ Yes ❑$_0$ No	❑$_1$ Inpatient ❑$_2$ Outpatient	❑$_3$ Both
b.	Heart stress test [e.g. with or without exercise (treadmill), pMIBI, MIBI, stress thallium, stress ECHO, dobutamine ECHO)]?	❑$_1$ Yes ❑$_0$ No	❑$_1$ Inpatient ❑$_2$ Outpatient	❑$_3$ Both
c.	Head CT or MRI for a condition other than headache or sinus trouble?	❑$_1$ Yes ❑$_0$ No	❑$_1$ Inpatient ❑$_2$ Outpatient	❑$_3$ Both
d.	Holter monitor?	❑$_1$ Yes ❑$_0$ No	❑$_1$ Inpatient ❑$_2$ Outpatient	❑$_3$ Both

If any tests or procedures were conducted, collect additional information on the **CVADMIN** form.

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Cardiovascular Event Questionnaire** Visit __ __ (Completed as Research Coordinator/Participant Interview)	Participant ID: Participant Initials: Site: Date:

1. **Since the last T Trial study contact**, has a ***doctor*** or ***healthcare*** provider told you that you had:

a.	a heart attack?	❑1 Yes	❑0 No
b.	a stroke or mini-stroke?	❑1 Yes	❑0 No
c.	atrial fibrillation?	❑1 Yes	❑0 No
d.	vascular (arterial) disease in the legs?	❑1 Yes	❑0 No
e.	angina?	❑1 Yes	❑0 No
f.	heart failure?	❑1 Yes	❑0 No

If ***YES*** to any of the above, and NOT associated with a hospitalization below, collect additional HCP information on the CVADMIN form.

2. Have you been ***hospitalized***, ***including an Emergency Department (ED) visit***, for any of the following medical problems since the last T Trial study contact?

			If YES, # of Hospitalizations / ED visits
a.	Heart attack or suspected heart attack (also called acute myocardial infarction or MI)?	❑1 Yes ❑0 No	___ ___ ___
b.	Chest pain due to heart disease, angina, unstable angina, or angina pectoris?	❑1 Yes ❑0 No	___ ___ ___
c.	Heart failure or congestive heart failure?	❑1 Yes ❑0 No	___ ___ ___
d.	Heart surgery to improve the circulation of the heart, coronary artery by-pass surgery, CABG; or percutaneous angioplasty, with or without a stent?	❑1 Yes ❑0 No	___ ___ ___
e.	Abnormal heart rhythm or heart arrhythmia?	❑1 Yes ❑0 No	___ ___ ___
f.	Stroke, mini-stroke or brain attack, transient ischemic attack (TIA), bleeding in the brain, hemorrhagic stroke, or intracranial hemorrhage?	❑1 Yes ❑0 No	___ ___ ___
g.	Blockage in blood vessels in your neck (carotid artery disease)?	❑1 Yes ❑0 No	___ ___ ___
h.	Blockage in blood vessels in your legs, or peripheral artery disease?	❑1 Yes ❑0 No	___ ___ ___
i.	Blood clots in the legs, deep venous thrombosis?	❑1 Yes ❑0 No	___ ___ ___
j.	***RC determines:*** If ***YES*** in 2a-2i, how many ***separate*** hospitalizations/ED visits since last T Trial study contact?		___ ___ ___

If any hospitalizations occurred, collect additional information on the CVADMIN form.

3. Have you had any of the following ***tests or procedures*** since the last T Trial study contact?

			If *YES*, was the procedure/test.....	
a.	Echocardiography (also called ultrasound of the heart)?	❑$_1$ Yes ❑$_0$ No	❑$_1$ Inpatient ❑$_2$ Outpatient	❑$_3$ Both
b.	Heart stress test [e.g. with or without exercise (treadmill), pMIBI, MIBI, stress thallium, stress ECHO, dobutamine ECHO)]?	❑$_1$ Yes ❑$_0$ No	❑$_1$ Inpatient ❑$_2$ Outpatient	❑$_3$ Both
c.	Head CT or MRI for a condition other than headache or sinus trouble?	❑$_1$ Yes ❑$_0$ No	❑$_1$ Inpatient ❑$_2$ Outpatient	❑$_3$ Both
d.	Holter monitor?	❑$_1$ Yes ❑$_0$ No	❑$_1$ Inpatient ❑$_2$ Outpatient	❑$_3$ Both
e.	Coronary Angiography (X Ray pictures of the arteries in your heart after inserting a long narrow tube into a blood vessel of your arm or leg and guiding it to your heart)	❑$_1$ Yes ❑$_0$ No	❑$_1$ Inpatient ❑$_2$ Outpatient	❑$_3$ Both

If any tests or procedures were conducted, collect additional information on the **CVADMIN** form.

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Cardiovascular-Metabolic History** Baseline (Completed as Research Coordinator/Participant Interview)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

CARDIAC HISTORY:

1. Have you ever been diagnosed with or has a doctor or other health professional ever told you that you had or have:

   a. Myocardial infarction (MI, heart attack)? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know

      1) If ***YES***, have you had 1, or more than 1, heart attack? ❑$_1$ One ❑$_2$ Two ❑$_3$ More than 2
      2) If ***YES***, how old were you when you had your **first** MI? ___ ___ years old ❑ Don't know
      3) If ***YES***, how old were you when you had your **second** MI? ___ ___ years old ❑ Don't know

   b. Angina (chest pain)? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
   c. Heart failure? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
   d. Atrial fibrillation or atrial flutter (an irregular heart rhythm)? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know

2. Have you ever had a revascularization procedure of your heart vessels (balloon angioplasty, coronary artery stenting, coronary artery bypass)? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know

CEREBROVASCULAR HISTORY:

3. Have you ever been diagnosed with or has a doctor or other health care professional ever told you that you had
   a. Stroke? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know
   b. Transient ischemic attack (TIA, ministroke)? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know

PERIPHERAL VASCULAR HISTORY:

4. Have you ever been diagnosed with or has a doctor or other health professional ever told you that you have peripheral vascular disease? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't Know

5. Do you have pain or cramping in your calves or legs ***(not due to arthritis)*** when walking that is relieved by resting? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't Know

6. Have you had a toe(s), foot, or leg surgically amputated due to infection or poor circulation? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't Know

7. Have you had a procedure to open blood vessels in your arms or legs (angioplasty, surgical vascular by-pass)? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't Know

HYPERTENSION HISTORY:

8. Has a doctor or other health professional ever told you that you have hypertension or high blood pressure? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't Know

   If ***NO***, skip to Question ***#9***.

   a. If ***YES***, how old were you when you were first told you had this condition? ___ ___ years old ❑ Don't know

   b. Have you ever taken medication for hypertension or high blood pressure? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know

   If ***NO***, skip to Question ***#9***.

   c. If **YES**, for how long have you, or did you, take medication for hypertension or high blood pressure? ___ ___ years ❑ Don't know

   d. Do you currently take prescribed medication for your hypertension or high blood pressure? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know

HIGH CHOLESTEROL HISTORY:

9. Has a doctor or other health professional ever told you that your blood cholesterol level was high? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know

   If **NO**, skip to Question **#10**.

   a. If ***YES***, how old were you when you were first told you had this condition? ___ ___ years old ❑ Don't know

   b. If **YES**, have you ever taken prescribed medication for high blood cholesterol? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know

   c. If **YES,** for how many years did you take, or have you taken, prescribed medication for high cholesterol? ___ ___ years ❑ Don't know

   d. Do you currently take prescribed medication for high blood cholesterol? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't know

---

DIABETIC HISTORY:

10. Has a doctor or other health professional ever told you that you have diabetes or high blood sugar? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't Know

    If NO, skip to Question #14.

    a. How old were you when a doctor first told you that you had diabetes? ___ ___ years old ❑ Don't know

    b. Are you currently taking insulin? ❑$_1$ Yes ❑$_0$ No

    c. Do you currently take diabetes pills to lower your blood sugar? (sometimes called oral agents) ❑$_1$ Yes ❑$_0$ No

    d. How old were you when you started taking diabetes medications? ___ ___ years old ❑ Don't know

11. Has a doctor ever told you that diabetes has affected your eyes or that you have retinopathy? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't Know

12. Has a doctor ever told you that you have diabetic neuropathy, that is, diabetes has affected the nerves of your hands or feet? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't Know

13. Has a doctor ever told you that you have diabetic nephropathy, that is, diabetes has affected your kidneys? ❑$_1$ Yes ❑$_0$ No ❑$_{88}$ Don't Know

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SMOKING HISTORY:

14. Have you smoked at least 100 cigarettes during your entire life? ***(approximately 5 packs)*** ❑$_1$ Yes ❑$_0$ No

    If ***NO***, skip to Question ***#19***.

15. How old were you when you first started smoking cigarettes regularly ***(3 or more times a week)***? ___ ___ years old
    ❑$_0$ Never smoked regularly
    ❑$_{88}$ Don't Know

16. Do you smoke cigarettes now? ❑1 Yes ❑0 No

    a. If ***NO***, at what age did you quit smoking cigarettes? ___ ___ years old ❑88 Don't Know

    b. If ***NO***, during the time you did smoke cigarettes, how many did you smoke?
    _____ ❑1 cigs/day
    _____ ❑2 packs/day
    _____ ❑3 less than 1 per day

17. How many cigarettes do you smoke per day? (***If known, write number and check either cigarettes/day or packs/day***)
    _____ ❑1 cigs/day
    _____ ❑2 packs/day
    _____ ❑3 less than 1 per day

18. How long have you smoked this amount? (***If known, write number and check either months or years***) ___ ___ ❑1 months ❑2 years

19. Have you ever smoked at least 20 cigars in your entire life? ❑1 Yes ❑0 No

20. Do you currently smoke cigars? ❑1 Yes ❑0 No

21. How many cigars do you smoke per day? ___ ___ cigars

CHRONIC LUNG DISEASE HISTORY:

22. Has a doctor or other health professional ever told you that you have emphysema or chronic obstructive pulmonary disease (COPD)? ❑1 Yes ❑0 No ❑88 Don't Know

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Cardiovascular Event Review** (Completed by the DCC & Reviewer)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Reported Event: _____

2. Corresponding AE Sequence Number: ___ ___

3. Status determination:

   ☐1 Cardiovascular Event Confirmed: The information in the medical records confirms the cardiovascular event reported.

   ☐2 Other Cardiovascular Event: The information in the medical record indicates this event is not the type of cardiovascular event reported. The actual cardiovascular event is: _____

   _____.

   ☐3 Cardiovascular Event Not Confirmed: The information in the medical record indicates that the reported event is not a cardiovascular event.

   ☐4 Unable to Determine if the Event is a Cardiovascular Event: The information in the medical record is insufficient to determine if the reported event is a cardiovascular event.

4. Comments: _____

   _____

_____ _____

Date e-signature

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Cardiovascular Trial Screening** Pre-screening (Completed by Research Coordinator)	Participant ID: _____ Participant Initials: _____ Site: ☐☐ Date: ____/____/_____

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

Ask the following questions to the participant:

1. Do you have an allergy to iodinated contrast medium? ❑$_1$ Yes ❑$_0$ No

2. Has a doctor or health care provider ever told you that you have atrial fibrillation? ❑$_1$ Yes ❑$_0$ No

3. Are you currently using metformin? ❑$_1$ 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** **Cardiovascular 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 CV 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** **Cardiovascular Trial Screening Visit 1** Screening Visit 1 (Completed by Research Coordinator)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Inclusion Criteria

Question 1 must be "YES" in order for the participant to be eligible.

1. Is the participant's eGFR greater than 60ml/min/1.73m^2? ❑$_1$ Yes ❑$_0$ No
   NOTE: Check estimated glomerular filtration (eGFR) as reported on the Quest lab report at SV1 or Month 12.

Exclusion Criteria

All responses to questions 2-5 must be "NO" in order for the participant to be eligible.

Ask the following questions to the participant:

2. Do you have an allergy to iodinated contrast medium? ❑$_1$ Yes ❑$_0$ No
3. Are you unable to hold your breath for 10 seconds? ❑$_1$ Yes ❑$_0$ No
4. Has a doctor or health care provider ever told you that you have an atrial fibrillation? ❑$_1$ Yes ❑$_0$ No
5. Has the participant ever had a coronary artery bypass graft? ❑$_1$ Yes ❑$_0$ No
6. Is participant eligible for the **Cardiovascular Trial** based on the inclusion and exclusion criteria? ❑$_1$ Yes ❑$_0$ No

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7. Is the participant currently using a pacemaker or defibrillator? ❑$_1$ Yes ❑$_0$ No
   a. If YES, is the participant being excluded for this reason? ❑$_1$ Yes ❑$_0$ No
8. Is the participant currently using metformin? ❑$_1$ Yes ❑$_0$ No
   a. If YES, is the participant being excluded for this reason? ❑$_1$ Yes ❑$_0$ No
9. Are there reasons other than eligibility that the clinical site deems this participant ineligible to participate in the Cardiovascular Trial? ❑$_1$ Yes ❑$_0$ No
   a. Please specify: _____

TESTOSTERONE TRIAL

CV Symptom Questionnaire

Visit Number: __ __

(Research Coordinator Completed)

Participant ID:__ __ __ __ __ __

Participant Initials __ __ __

Site: __ __

Date:__ __ / __ __ / __ __ __ __

Cardiac & Cerebrovascular Symptom Assessment

1. Cerebrovascular Symptoms (TIA & Stroke)

Since your last T Trial Visit…

a.	Have you had sudden painless weakness on one side of your body?	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Don't Know
b.	Have you had sudden numbness or a dead feeling on one side of your body?	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Don't Know
c.	Have you had painless loss of vision in one or both eyes?	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Don't Know
d.	Have you suddenly lost one half of your vision?	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Don't Know
e.	Have you suddenly lost the ability to understand what people are saying?	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Don't Know
f.	Have you suddenly lost the ability to express yourself orally or in writing?	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Don't Know

2. Cardiovascular Assessment (Angina)

Since your last T Trial Visit…

a.	Have you had pain or discomfort in your chest?	❑$_1$ Yes	❑$_0$ No (if **No**, skip to **Question 3**)	
b.	Did you get it when you walked uphill or hurried? (Record **Yes** if either **walking uphill or hurrying** causes pain or discomfort.)	❑$_1$ Yes	❑$_0$ No	❑$_{88}$ Never hurry or walk uphill
c.	Did you get it when you walk at an ordinary pace on level ground?	❑$_1$ Yes	. ❑$_0$ No	

If the answer to ***either*** question b or question c is "**Yes**," then answer question d.
If the answer to ***both*** questions b and c is "**No**", **skip to question 3.**

d.	What do you do if you get it while walking? (*****Record ***stop*** or ***slow down*** if subject carries on ***after*** taking nitroglycerin.)	❑$_1$ Stop or slow down ❑$_2$ Carry on *****
e.	If you stand still, what happens?	❑$_1$ Relieved ❑$_2$ Not Relieved
f.	How soon?	❑$_1$ 10 minutes or less ❑$_2$ More than 10 minutes
g.	What is the location in your body? (Check ***all*** that apply)	❑ Sternum - upper or middle ❑ Sternum – lower ❑ Left anterior chest ❑ Left arm ❑ Other _____

Cardiac & Cerebrovascular Symptom Assessment

Cardiovascular Assessment (Congestive Heart Failure)

3. Since your last T Trial Visit…

a. Have you had to sleep on 2 or more pillows to help you breathe? ❑1 Yes ❑0 No ❑88 Don't Know

b. Have you been awakened at night by trouble breathing? ❑1 Yes ❑0 No ❑88 Don't Know

c. Have you had swelling of your feet or ankles? ❑1 Yes ❑0 No ❑88 Don't Know

c1. ***If Yes to 3c***, did it tend to come on during the day and go down overnight? ❑1 Yes ❑0 No ❑88 Don't Know ❑99 Not Applicable

d. Do you become breathless when walking on level ground? ❑1 Yes ❑0 No ❑88 Don't Know

e. Do you become breathless when walking up hills or stairs? ❑1 Yes ❑0 No ❑88 Don't Know

f. Do you ever have to stop walking because of breathlessness? ❑1 Yes ❑0 No ❑88 Don't Know

4. Peripheral Vascular Disease Assessment

Since your last T Trial Visit…

a. Do you get pain in the back of your legs when you walk that stops with rest? ❑1 Yes ❑0 No ❑88 Don't Know

5. Other Symptoms

Since your last T Trial Visit…

a. Have you experienced any other symptoms or events that adversely affected your health? ❑1 Yes ❑0 No ❑88 Don't Know

If ***Yes***, describe: _____

b. Have you visited a physician or emergency room seeking help for those symptoms or events? ❑1 Yes ❑0 No ❑88 Don't Know ❑99 Not Applicable

c. Have you visited a physician or emergency room for any reason? ❑1 Yes ❑0 No ❑88 Don't Know ❑99 Not Applicable

If ***Yes***, describe: _____

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Demographic Information** Screening Visit 1 (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Date of Birth: __ __/__ __/__ __ __ __ (mm/dd/yyyy)

2. Ethnicity:
   - ☐1 Hispanic/Latino
   - ☐2 Not Hispanic/Latino

3. Race: (check all that apply)
   - ☐ North American Indian/Alaskan Native
   - ☐ Asian
   - ☐ Black/African American
   - ☐ Native Hawaiian/Other Pacific Islander
   - ☐ White/Caucasian
   - ☐ Other _____

4. Marital status:
   - ☐1 Never married
   - ☐2 Currently married
   - ☐3 Living with a partner
   - ☐4 Divorced
   - ☐5 Separated
   - ☐6 Widowed

5. Highest level of education completed:
   - ☐1 8th grade or less
   - ☐2 9th to 12th grade, no high school diploma
   - ☐3 High school graduate or equivalent (e.g. GED)
   - ☐4 Technical or vocational school degree
   - ☐5 Some college education, but not completed degree
   - ☐6 College graduate
   - ☐7 Professional or graduate degree (e.g. Master's, PhD, JD, MD)

6. Is participant visually impaired? ☐1 Yes ☐0 No

   If YES, does participant wear eye glasses or contacts? ☐1 Yes ☐0 No

7. Is participant hearing impaired? ☐1 Yes ☐0 No

   If YES, does participant use an assistive hearing device? ☐1 Yes ☐0 No

   If YES, on which ear is the device used?
   - ☐1 Right
   - ☐2 Left
   - ☐3 Both

8. Does the participant comprehend and respond in English? ☐1 Yes ☐0 No

INSTRUCTIONS

Below are listed a brief set of questions that ask about your sexual thoughts and activities. The questions are divided into five sections that ask about different aspects of your sexual experiences.

Some questions request that you answer in terms of "how often" you engage in certain sexual activities. Other questions ask you to report "how intense" some of your sexual experiences are. A third type of question inquires about how much you "enjoyed" or were "satisfied" by different aspects of your sexual activities and relationship.

For each Section, there are one or more scale definition boxes located alongside the questions. Indicators at the tops of the boxes tell you which questions the particular scale definition should be used with.

The inventory is quite brief, so please take your time in answering all the questions. **Please circle the scale number for each question that best describes your personal experience.** If you have any questions, please ask the person who gave you the inventory for help or clarification.

SECTION I - SEXUAL DESIRE

During the last 30 days, or since the last time you completed this inventory,

Questions 1a – 1d
7= 2 or more times a day
6= once a day
5= 4 to 6 times a week
4= 2 or 3 times a week
3= once a week
2= once or twice a month
1= less than once a month
0= Not at all

1a How often did you have thoughts or fantasies about sexual, romantic, or erotic situations?

0 1 2 3 4 5 6 7

1b How often did you feel sexual desire?

0 1 2 3 4 5 6 7

1c How often did you want to be involved in sexual activities?

0 1 2 3 4 5 6 7

1d With the partner of your choice, how often did you want to have sexual intercourse?

0 1 2 3 4 5 6 7

Question 1e
5= intense
4= very strong
3= strong
2= moderate
1= mild
0= absent

1e Usually, how strong was your sexual desire?

0 1 2 3 4 5

1f Sum of 1a – 1e _____
(Calculated by DMS.)

SECTION II - SEXUAL AROUSAL

During the last 30 days, or since the last time you filled out this inventory,

2a How often did you feel sexually aroused, that is have a satisfactory erection with or without your partner?

0 1 2 3 4 5 6 7

2b How often did you have a full erection upon awakening In the morning?

0 1 2 3 4 5 6 7

2c How often did you have an erection that enabled you to penetrate your partner during intercourse?

0 1 2 3 4 5 6 7

2d How often were you able to maintain a good erection to your satisfaction throughout sexual intercourse?

0 1 2 3 4 5 6 7

Questions 2a – 2d
7= 2 or more times a day
6= once a day
5= 4 to 6 times a week
4= 2 or 3 times a week
3= once a week
2= once or twice a month
1= less than once a month
0= Not at all

2e Please rate your ability to get and maintain an erection during this period?

0 1 2 3 4 5

Question 2e
5= excellent
4= good
3= fair
2= weak
1= very poor

2f Sum of 2a – 2e _____
(Calculated by DMS.)

SECTION III - SEXUAL ACTIVITY

3a How often have you engaged in kissing, petting or sexual touching with your partner?

0 1 2 3 4 5 6 7

3b How often have you engaged in masturbation?

0 1 2 3 4 5 6 7

3c How often have you initiated sexual experiences with your partner?

0 1 2 3 4 5 6 7

3d How often have you had sexual intercourse that led to orgasm for you or your partner?

0 1 2 3 4 5 6 7

3e How often have you engaged in other sexual activities that led to orgasm for you or your partner?

0 1 2 3 4 5 6 7

Questions 3a – 3d
7= 2 or more times a day
6= once a day
5= 4 to 6 times a week
4= 2 or 3 times a week
3= once a week
2= once or twice a month
1= less than once a month
0= Not at all

SECTION IV- ORGASM

During the last 30 days, or since the last time you filled out this inventory, (NOTE: If you did not experience an orgasm during this period circle "0" for these items)

Questions 4a – 4c
4= extremely (easy, intense, good)
3= very (easy, intense, good)
2= moderately (easy, intense, good)
1= minimally (easy, intense, good)
0= not at all (easy, intense, good)

4a How easy was it for you to have an orgasm?

0 1 2 3 4

4b Typically, how intense were your orgasms?

0 1 2 3 4

4c How good was the control or timing of your orgasms?

0 1 2 3 4

Questions 4d – 4e
7= 2 or more times a day
6= once a day
5= 4 to 6 times a week
4= 2 or 3 times a week
3= once a week
2= once or twice a month
1= less than once a month
0= Not at all

4d How often did you experience an orgasm

0 1 2 3 4 5 6 7

4e How often did you experience a sense of relaxation and feeling good after orgasm?

0 1 2 3 4 5 6 7

SECTION V - SEXUAL SATISFACTION

Questions 5a – 5e
5= highly satisfied
4= satisfied
3= somewhat satisfied
2= somewhat dissatisfied
1= dissatisfied
0= highly dissatisfied

5a How satisfied have you been with your sexual relationship with your partner?

0 1 2 3 4 5

5b How satisfied have you been with the emotional intimacy and closeness you have shared with your partner?

0 1 2 3 4 5

5c How satisfied have you been with how often you have had sex?

0 1 2 3 4 5

5d How satisfied have you been with the variety of your sexual experiences?

0 1 2 3 4 5

5e How satisfied have you been with the sexual enjoyment you have experienced with your partner?

0 1 2 3 4 5

Participant Initials __ __ __ Date __ __/ __ __/ __ __ __ __

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **DRUG DISTRIBUTION** Visit __ __ (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Were the gel application instructions reviewed? ☐1 Yes ☐0 No

2. Did the participant agree to comply with the instructions? ☐1 Yes ☐0 No

3. Was any gel retuned at this visit? ☐1 Yes ☐0 No
   (If **YES** complete Line #1 below)

4. What was the date of the most recent application of the gel? __ __ / __ __ / __ __ __ __ ☐99 N/A
   M M D D Y Y Y Y

   4a. What was the time of the most recent application of the gel? ____:____ ☐ AM ☐ PM
   HH MM

5. Was a gel bottle dispensed at this visit? ☐1 Yes ☐0 No
   (If **YES** complete Line #2 below)

Line Number	**Date** (mm/dd/yyy)	**Kit Number**	**Number of Bottles Dispensed**	**Daily Number of Depressions**	**Quantity Dispensed in gms**	**Dispensed By**	**Number of Bottles Returned**	**Amount Returned in gms**	**Comments**
1			☐99 N/A	☐99 N/A	☐99 N/A	☐99 N/A			
2							☐99 N/A	☐99 N/A	

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **DRUG LABEL** *(Administrative CRF)*	Participant ID:__ __ __ __ __ ___ Participant Initials __ __ __ Site: __ __

Record of Starter Kit and Re-supply Dispensed	
Starter Kit ⬇	**Re-supply 1** ⬇
0 Place tear off label here	1 Place tear off label here
Comments:	Comments:
Re-supply 2 ⬇	**Re-supply 3** ⬇
2 Place tear off label here	3 Place tear off label here
Comments:	Comments:
Re-supply 4 ⬇	**Re-supply 5** ⬇
4 Place tear off label here	5 Place tear off label here
Comments:	Comments:

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **DOCUMENT CHECKLIST** **ADMINISTRATIVE FORM** (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

DMS tracking number: ___ ___ ___

Admission Date: _____ Discharge Date: _____

MEDICAL RECORDS	MI	Stroke	Outpatient Diagnosis	Procedure	
HCP summary/chart documentation			☐		
Emergency Dept. physician note	☐	☐			
Admission note	☐	☐			
Selected daily progress notes	☐**(a)**	☐**(d)**			
Discharge summary	☐	☐			
Cardiologist notes	☐**(a)**				
Neurologist notes		☐**(d)**			
CT scans or CT angiograms		☐			
Magnetic resonance imaging		☐			
Magnetic resonance angiography		☐			
Angiograms		☐			
Carotid ultrasound		☐			
Cardiac catheterizations	☐				
Rhythm strips					
Electrocardiograms (ECG)	☐**(b)**				
Chest X-rays					
Pulmonary artery (Swan-Ganz) catheterization readings (wedge pressure, cardiac index, etc.)					
Peripheral vascular arteriogram or angioplasty					
Coronary artery bypass	☐				
Cardioverter or pacemaker implantation					
Neurologic operations		☐			
Peripheral vascular amputations					
Cardiac enzymes	☐**(c)**				
Brain natriuretic peptide					
Lumbar puncture results		☐			
Other: _____					

(a) Copy all progress notes starting 48 hours before and ending 48 hours after the sets of cardiac enzymes and ECGs were performed to rule in or rule out MI and acute coronary syndrome (in the case of MI/ACS)
(b) Copy ECGs from 48 hours before until 48 hours after event; also include admission ECG and last ECG before discharge
(c) Includes CK, CK-MB, Troponin-I, Troponin-T, LDH, LDH1, and LDH2, if available
(d) Copy all progress notes starting 48 hours before and ending 48 hours after the cerebrovascular event

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Dose Change Notification Log** (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Record start date when study drug is first administered. Thereafter, record a start/stop date only when the dose is changed.

Line #	Start Date	Stop Date	Daily Dose
	mm/dd/yyyy	mm/dd/yyyy	
1	__ __ / __ __ / __ __ __ __	__ __ / __ __ / __ __ __ __	__ __ depressions / day
2	__ __ / __ __ / __ __ __ __	__ __ / __ __ / __ __ __ __	__ __ depressions / day
3	__ __ / __ __ / __ __ __ __	__ __ / __ __ / __ __ __ __	__ __ depressions / day
4	__ __ / __ __ / __ __ __ __	__ __ / __ __ / __ __ __ __	__ __ depressions / day
5	__ __ / __ __ / __ __ __ __	__ __ / __ __ / __ __ __ __	__ __ depressions / day
6	__ __ / __ __ / __ __ __ __	__ __ / __ __ / __ __ __ __	__ __ depressions / day
7	__ __ / __ __ / __ __ __ __	__ __ / __ __ / __ __ __ __	__ __ depressions / day
8	__ __ / __ __ / __ __ __ __	__ __ / __ __ / __ __ __ __	__ __ depressions / day
9	__ __ / __ __ / __ __ __ __	__ __ / __ __ / __ __ __ __	__ __ depressions / day
10	__ __ / __ __ / __ __ __ __	__ __ / __ __ / __ __ __ __	__ __ depressions / day
11	__ __ / __ __ / __ __ __ __	__ __ / __ __ / __ __ __ __	__ __ depressions / day
12	__ __ / __ __ / __ __ __ __	__ __ / __ __ / __ __ __ __	__ __ depressions / day

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL**	Participant ID:__ __ __ __ __ __
	ELIGIBILITY	Site: __ __
	(Research Coordinator Completed)	Date:__ __ / __ __ / __ __ __ __

COMMON INCLUSION CRITERIA
All responses to questions 1-2 must be "YES" in order for the participant to be eligible.

1. Participant is ≥ 65 years old.	☐1 Yes	☐0 No
2. Participant's total serum testosterone concentration ≥ 100 and ≤ 250 ng/dL at 8 -10 AM at each of two screening visits.	☐1 Yes	☐0 No

COMMON EXCLUSION CRITERIA
All responses to questions 3-20 must be "NO" in order for the participant to be eligible.

3. Participant has diagnosed prostate cancer or prostatic intraepithelial neoplasia (PIN) or, by the Prostate Cancer Risk Calculator, a >30% risk of having overall prostate cancer or >7% risk of having high grade prostate cancer.	☐1 Yes	☐0 No
4. Participant has severe lower urinary tract symptoms (score of ≥ 19) by the International Prostate Symptom Score questionnaire.	☐1 Yes	☐0 No
5. Participant has hemoglobin <10 g/dL or >16.0 g/dL.	☐1 Yes	☐0 No
6. Participant has sleep apnea, diagnosed but untreated.	☐1 Yes	☐0 No
7. Participant has a history of alcohol or substance abuse within the past year (based on self report).	☐1 Yes	☐0 No
8. Participant has angina not controlled by treatment, NYHA class III or IV congestive heart failure, or myocardial infarction within 3 months before entry.	☐1 Yes	☐0 No
9. Participant has severe pulmonary disease that precludes physical function tests.	☐1 Yes	☐0 No
10. Participant has a serum creatinine > 2.2 mg/dL and is being treated by dialysis.	☐1 Yes	☐0 No
11. Participant has ALT 3x upper limit of normal.	☐1 Yes	☐0 No
12. Participant has hemoglobin A1c > 9%.	☐1 Yes	☐0 No
13. Participant has an exclusionary cancer.	☐1 Yes	☐0 No
14. Participant has body mass index (BMI) >35 kg/m^2.	☐1 Yes	☐0 No
15. Participant has Mini Mental State Exam (MMSE) Score < 24.	☐1 Yes	☐0 No
16. Participant has untreated moderate or severe depression as defined by a score of >14 on the PHQ-9 questionnaire. (Subjects with depression who have been stable for more than three months while taking an antidepressant medication are eligible.)	☐1 Yes	☐0 No
17. Participant has been diagnosed with Axis I disorder such as schizophrenia or bipolar disease.	☐1 Yes	☐0 No
18. Participant has a generalized skin condition such as psoriasis or eczema that might affect testosterone absorption or tolerability of the testosterone gel.	☐1 Yes	☐0 No
19. Participant has known skin intolerance to alcohol or allergy to any of the ingredients of testosterone gel.	☐1 Yes	☐0 No

20. Has participant used any of the following medications within the time frames defined:

a. Medications that affect serum testosterone concentration (eg, testosterone, androstenedione, DHEA, estrogens, GnRH analogs, spironolactone, ketoconazole) for more than 2 months during the previous 12 months, or within the past 3 months.	☐1 Yes	☐0 No
b. rhGH or megesterol acetate for more than 2 months within the previous 12 months or within the past 3 months.	☐1 Yes	☐0 No
c. Anti-depressant medication that has been introduced within the past 3 months.	☐1 Yes	☐0 No
d. Anti-psychotic medication for Axis I disorder within the past 3 months.	☐1 Yes	☐0 No
e. Prednisone use daily for more than 2 weeks, or equivalent doses of other glucocorticoids for more than 2 weeks during the previous 3 months.	☐1 Yes	☐0 No
f. Opiate abuse within the past 3 months.	☐1 Yes	☐0 No

Physical Function ☐99 **N/A** ***(Check N/A if participant is not eligible or did not consent.)***

INCLUSION CRITERIA

Responses to questions below must be "YES" in order for the participant to be eligible.

21. Participant is ambulatory, with or without a device for assistance, such as a cane or walker.	☐1 Yes	☐0 No
22. Participant has self reported difficulty in walking one-quarter mile.	☐1 Yes	☐0 No
23. Participant has walking speed <1 m/sec on the 6 minute walk test.	☐1 Yes	☐0 No

EXCLUSION CRITERIA

Response to question below must be "NO" in order for the participant to be eligible.

24. Participant has a condition affecting mobility of sufficient severity that testosterone is unlikely to improve, including neurological conditions (stroke, multiple sclerosis) and severe disabling arthritis of the lower extremity, joints, or back.	☐1 Yes	☐0 No

Sexual Function ☐99 **N/A** ***(Check N/A if participant is not eligible or did not consent.)***

INCLUSION CRITERIA

Responses to questions below must be "YES" in order for the participant to be eligible.

25. Participant has decreased libido, defined by a score of ≤ 20 on the DISF-M-II SR questionnaire.	☐1 Yes	☐0 No
26. Participant has sexual partner willing to have sexual intercourse ≥ twice/month.	☐1 Yes	☐0 No

EXCLUSION CRITERIA

Responses to questions below must be "NO" in order for the participant to be eligible.

27. Participant has medical or nonmedical reasons that would preclude sexual activity (e.g., penile deformity, Peyronie's disease, pelvic surgery for bladder cancer, medical illness).	☐1 Yes	☐0 No

28. Participant has an absence of pedal pulses as an indication of severe peripheral vascular disease.	☐1 Yes	☐0 No
29. Participant has autonomic neuropathy.	☐1 Yes	☐0 No

Vitality ☐99 **N/A** ***(Check N/A if participant is not eligible or did not consent.)***

INCLUSION CRITERIA

Responses to questions below must be "YES" in order for the participant to be eligible.

30. Participant has self reported decreased energy.	☐1 Yes	☐0 No
31. Participant has low vitality, defined by a score <40 on the FACIT – fatigue scale.	☐1 Yes	☐0 No

Anemia

INCLUSION CRITERIA

Response to question below must be "YES" in order for the participant to be eligible.

32. Participant has hemoglobin concentration between ≥ 10.0 and < 13.5 g/dL, *(13.5 g/dL is the lower limit of normal for the central laboratory)*	☐1 Yes	☐0 No

Protocol Eligibility Determination

33. Is participant eligible for the **Testosterone Trial** based on the general inclusion and exclusion criteria? ***Participant is eligible if only the shaded responses are selected for questions 1 – 20.***	☐1 Yes	☐0 No

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Eligibility 2** (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

COMMON INCLUSION CRITERIA
All responses to questions 1-2 must be "YES" in order for the participant to be eligible.

1. Participant is ≥ 65 years old.	☐1 Yes	☐0 No
2. Participant's total serum testosterone concentration is within eligible ranges: SV1 Testosterone level < 275 ng/dL SV2 Testosterone level < 300 ng/dL Mean of SV1 and SV2 Testosterone level < 275 ng/dL	☐1 Yes	☐0 No

COMMON EXCLUSION CRITERIA
All responses to questions 3-24 must be "NO" in order for the participant to be eligible.

3. Participant has diagnosed prostate cancer or prostatic intraepithelial neoplasia (PIN) or, by the Prostate Cancer Risk Calculator, a >35% risk of having overall prostate cancer or >7% risk of having high grade prostate cancer.	☐1 Yes	☐0 No
3a. Does the participant have a prostate nodule?	☐1 Yes	☐0 No
3b. If **YES**, has the nodule been evaluated and the participant approved to continue in the trial? (3b must be "YES" for the participant to be eligible.)	☐1 Yes	☐0 No
4. Participant has severe lower urinary tract symptoms (score of > 19) by the International Prostate Symptom Score questionnaire.	☐1 Yes	☐0 No
5. Participant has hemoglobin <10 g/dL or >16.0 g/dL.	☐1 Yes	☐0 No
6. Participant has sleep apnea, diagnosed but untreated.	☐1 Yes	☐0 No
7. Participant has a history of alcohol or substance abuse within the past year (based on self report).	☐1 Yes	☐0 No
8. Participant has or had angina not controlled by treatment, before entry.	☐1 Yes	☐0 No
9. Participant has or had NYHA class III or IV congestive heart failure, or myocardial infarction within the previous 3 months.	☐1 Yes	☐0 No
10. Participant had a stroke within the previous 3 months.	☐1 Yes	☐0 No
11. Participant has hypertension defined as a systolic blood pressure >160mm Hg or a diastolic blood pressure > 100mm Hg.	☐1 Yes	☐0 No
12. Participant has severe pulmonary disease that precludes physical function tests.	☐1 Yes	☐0 No
13. Participant has a serum creatinine > 2.2 mg/dL.	☐1 Yes	☐0 No
13a. Participant has TSH value > 7.5 MCIU/ML	☐1 Yes	☐0 No
14. Participant is being treated by dialysis.	☐1 Yes	☐0 No
15. Participant has ALT 3x upper limit of normal.	☐1 Yes	☐0 No
16. Participant has hemoglobin A1c > 8.5%.	☐1 Yes	☐0 No
17. Participant has an exclusionary cancer.	☐1 Yes	☐0 No

18. Participant has body mass index (BMI) >37 kg/m^2.	☐$_1$ Yes	☐$_0$ No
19. Participant has Mini Mental State Exam (MMSE) Score < 24.	☐$_1$ Yes	☐$_0$ No
20. Participant has untreated moderate or severe depression as defined by a score of >14 on the PHQ-9 questionnaire. (Subjects with depression who have been stable for more than three months while taking an antidepressant medication are eligible.)	☐$_1$ Yes	☐$_0$ No
21. Participant has been diagnosed with a major psychiatric disorder that is untreated, unstable, has resulted in hospitalization or medication change within the previous three months, or would result in inability to complete the trial efficacy instruments.	☐$_1$ Yes	☐$_0$ No
22. Participant has a generalized skin condition such as psoriasis or eczema that might affect testosterone absorption or tolerability of the testosterone gel.	☐$_1$ Yes	☐$_0$ No
23. Participant has known skin intolerance to alcohol or allergy to any of the ingredients of testosterone gel.	☐$_1$ Yes	☐$_0$ No
24. Has participant used any of the following medications within the time frames defined:		
24a. Medications that affect serum testosterone concentration (eg, testosterone, androstenedione, DHEA, estrogens, GnRH analogs, spironolactone, ketoconazole) for more than 2 months during the previous 12 months, or within the past 3 months.	☐$_1$ Yes	☐$_0$ No
24b. rhGH or megesterol acetate for more than 2 months within the previous 12 months or within the past 3 months.	☐$_1$ Yes	☐$_0$ No
24c. Anti-depressant medication that has been introduced within the past 3 months.	☐$_1$ Yes	☐$_0$ No
24d. Anti-psychotic medication for Axis I disorder within the past 3 months.	☐$_1$ Yes	☐$_0$ No
24e. Prednisone use daily for more than 2 weeks, or equivalent doses of other glucocorticoids for more than 2 weeks during the previous 3 months.	☐$_1$ Yes	☐$_0$ No
24f. Opiate abuse within the past 3 months.	☐$_1$ Yes	☐$_0$ No

Physical Function

INCLUSION CRITERIA

For the participant to be eligible, question 25 must be Yes, questions 26 **or** 26a must be Yes, question 27 must be Yes, and Question 28 must be No.

25. Participant is ambulatory, with or without a device for assistance, such as a cane or walker.	☐$_1$ Yes	☐$_0$ No
26. Participant has self reported difficulty in walking one-quarter mile.	☐$_1$ Yes	☐$_0$ No
26a. Participant has self reported difficulty in climbing one flight of stairs.	☐$_1$ Yes	☐$_0$ No
27. Participant has walking speed <1.2 m/sec on the 6 minute walk test.	☐$_1$ Yes	☐$_0$ No

EXCLUSION CRITERIA

Response to question below must be “NO” in order for the participant to be eligible.

28. Participant has a condition affecting mobility of sufficient severity that testosterone is unlikely to improve, including neurological conditions (stroke, multiple sclerosis) and severe disabling arthritis of the lower extremity, joints, or back.	☐$_1$ Yes	☐$_0$ No

Sexual Function

INCLUSION CRITERIA

Responses to question below must be "YES" in order for the participant to be eligible.

29. Participant has decreased libido, defined by a score of ≤ 20 on the DISF-M-II SR questionnaire.	☐1 Yes	☐0 No
29a. Participant has self reported decreased libido	☐1 Yes	☐0 No
30. If YES, Participant has a sexual partner willing to have sexual intercourse ≥ twice/month.	☐1 Yes	☐0 No

EXCLUSION CRITERIA

Responses to questions below must be "NO" in order for the participant to be eligible.

31. Participant has medical or nonmedical reasons that would preclude sexual activity (e.g., penile deformity, Peyronie's disease, pelvic surgery for bladder cancer, medical illness).	☐1 Yes	☐0 No
32. Participant has an absence of pedal pulses as an indication of severe peripheral vascular disease.	☐1 Yes	☐0 No
33. Participant has autonomic neuropathy.	☐1 Yes	☐0 No

Vitality

INCLUSION CRITERIA

Responses to questions below must be "YES" in order for the participant to be eligible.

34. Participant has self reported decreased energy.	☐1 Yes	☐0 No
35. Participant has low vitality, defined by a score <40 on the FACIT – fatigue scale.	☐1 Yes	☐0 No

Anemia

INCLUSION CRITERIA

Response to question below must be "YES" in order for the participant to be eligible.

36. Participant has hemoglobin concentration between ≥ 10.0 and < 13.5 g/dL, *(13.5 g/dL is the lower limit of normal for the central laboratory)*	☐1 Yes	☐0 No

Protocol Eligibility Determination

37. Is participant eligible for the **Testosterone Trial** based on the general inclusion and exclusion criteria? ***Participant is eligible if only the shaded responses are selected for questions 1 – 24.***	☐1 Yes	☐0 No

38. Are there reasons other than eligibility or screening criteria that the clinical site deems this participant ineligible to participate in the TTRIAL?	☐1 Yes	☐0 No

a. If YES, specify reason(s): _____

39. Is your site currently approved and willing to enroll participants with a testosterone level < 100 ng/dL?	☐1 Yes	☐0 No

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

Instructions: Complete CRF after consent is obtained for enrollment in the epigenetics study after 6 months of treatment.

1. Particiant agreed to be in optional epigenetics study? ❑$_1$ Yes ❑$_0$ No
2. Participant agreed to have DNA/RNA shared for research on testosterone? ❑$_1$ Yes ❑$_0$ No
3. Participant agreed to have DNA/RNA shared for research on any disease? ❑$_1$ Yes ❑$_0$ No

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Epigenetics Screening Form** Screening Visit 1 (Completed by Research Coordinator)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Instructions: Complete CRF after consent is obtained for enrollment in the genetics study at Screening Visit 1.

1. Participant agreed to have screening RNA/DNA used for genetics research? ❑$_1$ Yes ❑$_0$ No
2. Participant agreed to have DNA/RNA shared for research on testosterone? ❑$_1$ Yes ❑$_0$ No
3. Participant agreed to have DNA/RNA shared for research on any disease? ❑$_1$ Yes ❑$_0$ No

Participant agreed to have screening RNA/DNA submitted to NIH GWAS database:

4. Participant agreed to have GWAS shared for research on testosterone? ❑$_1$ Yes ❑$_0$ No
5. Participant agreed to have GWAS shared for research on any disease? ❑$_1$ Yes ❑$_0$ No

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **FACIT-Fatigue Scale** Visit __ __ (Participant Completed via IVR)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Below is a list of statements that other people with your illness have said are important. **By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>**

		Not at all	A little bit	Some-what	Quite a bit	Very much
1.	I feel fatigued.	☐0	☐1	☐2	☐3	☐4
2.	I feel weak all over.	☐0	☐1	☐2	☐3	☐4
3.	I feel listless (“washed out”).	☐0	☐1	☐2	☐3	☐4
4.	I feel tired.	☐0	☐1	☐2	☐3	☐4
5.	I have trouble starting things because I am tired.	☐0	☐1	☐2	☐3	☐4
6.	I have trouble finishing things because I am tired.	☐0	☐1	☐2	☐3	☐4
7.	I have energy.	☐0	☐1	☐2	☐3	☐4
8.	I am able to do my usual activities.	☐0	☐1	☐2	☐3	☐4
9.	I need to sleep during the day.	☐0	☐1	☐2	☐3	☐4
10.	I am too tired to eat.	☐0	☐1	☐2	☐3	☐4
11.	I need help doing my usual activities.	☐0	☐1	☐2	☐3	☐4
12.	I am frustrated by being too tired to do the things I want to do.	☐0	☐1	☐2	☐3	☐4
13.	I have to limit my social activity because I am tired.	☐0	☐1	☐2	☐3	☐4

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **FALLS- Baseline** (Participant Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Have you fallen over the past year, that is, when you went down unintentionally and landed on the floor or ground? ☐$_{1}$ Yes ☐$_{0}$ No ☐$_{88}$ Don't Know ☐$_{97}$ Refused

   1a. If YES, how many times have you fallen? __ __Number of Times ☐$_{88}$ Don't Know ☐ $_{97}$ Refused

   1b. If YES, when you fell, did you suffer any injury that required you to go to the doctor or to an emergency room, hospital, or urgent care center? ☐$_{1}$ Yes ☐$_{0}$ No ☐$_{88}$ Don't Know ☐$_{97}$ Refused

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **FALLS FOLLOW-UP** Visit __ __ (Participant Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1.	Since your last visit have you had any falls, that is, when you went down unintentionally and landed on the floor or ground?	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused
	a. If you answered "Yes" to question # 1, how many times would you say you've fallen since your last visit?	__ __Number of Times			
	b. If you answered "Yes" to question #1, did you see a doctor (or go to the ER) because of these falls?	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused
2.	Since your last visit, did a doctor tell you that you fractured or broke a bone?	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused
	a. If you answered "Yes" to question #2, what bone(s) were you told were broken:				
	Wrist	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused
	Hip	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused
	Spine	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused
	Other (specify):_____	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused
	b. If you answered "Yes" to question #2a, did you have an x-ray?	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused
	c. If you answered "Yes" to question #2b, did you go to an emergency room or stay overnight at a hospital for this problem?	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused
	d. How did the injury occur?				
	Fall from standing height or less	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused
	Fall from stairs, steps or curb	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused
	Fall from more than standing height	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused
	Trauma other than a fall	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused
	Minimal to moderate trauma (eg collisions during normal activities)	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused
	Severe trauma (eg motor vehicle accident)	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Don't Know	☐$_{97}$ Refused

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Fracture Information** Administrative (Completed by the Site)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

INSTRUCTIONS:

Use this administrative form to collect information to assess fractures.

1. Type of visit

   ☐ Hospitalization

   ☐ Emergency Department visit

   ☐ Physician's office visit

   ☐ Procedure or test

   ☐ Imaging study

2. Dates: _____ to _____

3. Name of Institution: _____

4. Address of Institution: _____

5. Treating, diagnosing or ordering physician (if known): _____

Additional Info:

_____

_____

_____

_____

_____

NOTE: Do not send to DCC.

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Fracture Confirmation** Administrative (Completed by the Site & DCC)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Corresponding AE Sequence Number: ___ ___

Confirm information reported in FALLSF report with the participant:

2. Did you see a doctor, go to the Emergency Department, or were hospitalized for this reported fracture?
   - ☐ Yes - Continue with form
   - ☐ No - Fax or email form to DCC

3. Reported fracture location (check all that apply):

   ☐ Wrist ☐ Hip ☐ Spine ☐ Other, specify _____

4. Did you receive an X-ray, CT scan, or MRI or other imaging study of the fracture: ☐ Yes ☐ No

5. Briefly describe how the injury occurred.

_____

_____

_____

INSTRUCTIONS:

NOTE: The information in the above section will be provided to the SFCC along with the acquired reports.

Submit this form with the medical records, notes, reports, and summaries for this reported fraction to the DCC.

Check all items below that are included in this packet:

☐ FRACTCONFIRM

☐ X-ray report

☐ CT Scan report

☐ MRI Scan report

☐ Other Imaging report, specify: _____

☐ Hospital or Emergency Department summary

☐ Operative note (Report or summary of procedure)

☐ Orthopedist note (Report or summary of orthopedic assessment or consultation)

☐ Other physician note (Report or summary of injury from primary care practitioner or other health care provider)

Specify: _____

INSTRUCTIONS: These questions ask about your sex life <u>over the past 4 weeks</u>. Please answer the following questions as honestly and clearly as possible. In answering these questions, the following definitions apply:

Sexual activity includes intercourse, caressing, foreplay and masturbation
Sexual intercourse is defined as vaginal penetration of the partner (you entered your partner)
Sexual stimulation includes situations like foreplay with a partner, looking at erotic pictures, etc.
Ejaculate the ejection of semen from the penis (or the feeling of this)

Check <u>ONLY</u> one box per question.

1. <u>Over the past 4 weeks</u>, how often were you able to get an erection during sexual activity?

   ☐ 0 No sexual activity
   ☐ 1 Almost never or never
   ☐ 2 A few times (much less than half the time)
   ☐ 3 Sometimes (about half the time)
   ☐ 4 Most times (much more than half the time)
   ☐ 5 Almost always or always

2. <u>Over the past 4 weeks</u>, when you had erections with sexual stimulation, how often were your erections hard enough for penetration?

   ☐ 0 No sexual activity
   ☐ 1 Almost never or never
   ☐ 2 A few times (much less than half the time)
   ☐ 3 Sometimes (about half the time)
   ☐ 4 Most times (much more than half the time)
   ☐ 5 Almost always or always

The next three questions will ask about the erections you may have had during sexual intercourse.

3. <u>Over the past 4 weeks</u>, when you attempted sexual intercourse, how often were you able to penetrate (enter) your partner?

   ☐ 0 Did not attempt intercourse
   ☐ 1 Almost never or never
   ☐ 2 A few times (much less than half the time)
   ☐ 3 Sometimes (about half the time)
   ☐ 4 Most times (much more than half the time)
   ☐ 5 Almost always or always

4. Over the past 4 weeks, during sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?

   ☐0 Did not attempt intercourse
   ☐1 Almost never or never
   ☐2 A few times (much less than half the time)
   ☐3 Sometimes (about half the time)
   ☐4 Most times (much more than half the time)
   ☐5 Almost always or always

5. Over the past 4 weeks, during sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?

   ☐0 Did not attempt intercourse
   ☐1 Extremely difficult
   ☐2 Very difficult
   ☐3 Difficult
   ☐4 Slightly difficult
   ☐5 Not difficult

6. Over the past 4 weeks, how many times have you attempted sexual intercourse?

   ☐0 No attempts
   ☐1 One to two attempts
   ☐2 Three to four attempts
   ☐3 Five to six attempts
   ☐4 Seven to ten attempts
   ☐5 Eleven or more attempts

7. Over the past 4 weeks, when you attempted sexual intercourse, how often was it satisfactory for you?

   ☐0 Did not attempt intercourse
   ☐1 Almost never or never
   ☐2 A few times (much less than half the time)
   ☐3 Sometimes (about half the time)
   ☐4 Most times (much more than half the time)
   ☐5 Almost always or always

8. Over the past 4 weeks, when you attempted sexual intercourse, how much have you enjoyed sexual intercourse?

☐0 No intercourse
☐1 No enjoyment
☐2 Not very enjoyable
☐3 Fairly enjoyable
☐4 Highly enjoyable
☐5 Very highly enjoyable

9. Over the past 4 weeks, when you had sexual stimulation or intercourse, how often did you ejaculate?

☐0 No sexual stimulation/intercourse
☐1 Almost never or never
☐2 A few times (much less than half the time)
☐3 Sometimes (about half the time)
☐4 Most times (much more than half the time)
☐5 Almost always or always

10. Over the past 4 weeks, when you had sexual stimulation or intercourse, how often did you have the feeling of orgasm or climax?

☐0 No sexual stimulation/intercourse
☐1 Almost never or never
☐2 A few times (much less than half the time)
☐3 Sometimes (about half the time)
☐4 Most times (much more than half the time)
☐5 Almost always or always

The next two questions ask about sexual desire. Let's define Sexual Desire as a feeling that may include wanting to have a sexual experience (for example masturbation or intercourse), thinking about having sex, or feeling frustrated due to lack of sex.

11. Over the past 4 weeks, how often have you felt sexual desire?

☐1 Almost never or never
☐2 A few times (much less than half the time)
☐3 Sometimes (about half the time)
☐4 Most times (much more than half the time)
☐5 Almost always or always

12. Over the past 4 weeks, how would you rate your level of sexual desire?

☐1 Very low or not at all
☐2 Low
☐3 Moderate
☐4 High
☐5 Very high

13. Over the past 4 weeks, how satisfied have you been with your overall sex life?

☐1 Very dissatisfied
☐2 Moderately dissatisfied
☐3 About equally satisfied and dissatisfied
☐4 Moderately satisfied
☐5 Very satisfied

14. Over the past 4 weeks, how satisfied have you been with your sexual relationship with your partner?

☐1 Very dissatisfied
☐2 Moderately dissatisfied
☐3 About equally satisfied and dissatisfied
☐4 Moderately satisfied
☐5 Very satisfied

15. Over the past 4 weeks, how do you rate your confidence that you can get and keep an erection?

☐1 Very low
☐2 Low
☐3 Moderate
☐4 High
☐5 Very high

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **International Prostate Symptom Score** Visit __ __ (Participant Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Your Score

1. Incomplete Emptying:
   Over the past month, how often have you had a sensation of not emptying your bladder completely after you finish urinating? _____
2. Frequency:
   Over the past month, how often have you have to urinate again less than two hours after you finished urinating? _____
3. Intermittency:
   Over the last month, how often have you found you stopped and started again several times when you urinated? _____
4. Urgency:
   Over the last month, how difficult have you found it to postpone urination? _____
5. Weak Stream:
   Over the past month, how often have you had a weak urinary stream? _____
6. Straining:
   Over the past month, how often have you had to push or strain to begin urination? _____

Questions 1 -6
0= Not at all
1= Less than 1 time in 5
2= Less than half time
3= About half the time
4= More than half time
5= Almost Always

7. Nocturia:
   Over the past month, how many times did you typically get up to urinate from the time you went to bed until the time you got up in the morning? _____

Question 7
1= 1 time
2= 2 times
3= 3 times
4= 4 times
5= 5 times

8. Quality of life due to urinary symptoms:
   If you were to spend the rest of your life with your urinary condition the way it is now, how would you feel about that? _____

Question 8
0= Delighted
1= Pleased
2= Mostly Satisfied
3= Mixed-About equally satisfied and dissatisfied
4= Mostly Dissatisfied
5= Unhappy
6= Terrible

.

9. Total Score: _____
   (Calculated by DMS.)

Participant Initials __ __ __ Date __ __/ __ __ /__ __ __ __

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Memory Complaint Questionnaire** Visit __ __ (Participant Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Compared to when you were in high school or college, how would you describe your ability to perform the following tasks involving your memory?

	Much better now	**Somewhat better now**	**About the same**	**Somewhat poorer now**	**Much poorer now**
1. Remembering the name of a person just introduced to you	☐1	☐2	☐3	☐4	☐5
2. Recalling telephone numbers or zip codes that you use on a daily or weekly basis	☐1	☐2	☐3	☐4	☐5
3. Recalling where you have put objects (such as keys) in your home or office	☐1	☐2	☐3	☐4	☐5
4. Remembering specific facts from a newspaper or magazine article you have just finished reading	☐1	☐2	☐3	☐4	☐5
5. Remembering the item(s) you intended to buy when you arrive at the grocery store or pharmacy	☐1	☐2	☐3	☐4	☐5
6. In general, how would you describe your memory as compared to when you were in high school	☐1	☐2	☐3	☐4	☐5

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Medical History 1** Screen Visit 1 (Research Coordinator Completed)	Participant ID: Participant Initials Site: Date:

1. Has a doctor ever told you that you have heart failure or congestive heart failure? ☐1 Yes ☐0 No
If YES, answer question 1a.

   1a. Does this condition prevent you from walking two or three blocks or up a flight of stairs? ***If YES, ineligible***. ☐1 Yes ☐0 No

2. Has a doctor ever told you that you have chronic lung disease such as chronic bronchitis, COPD, asthma, or emphysema? **If YES, answer question 2a.** ☐1 Yes ☐0 No

   2a. Does this condition require you to wear oxygen? ***If YES, ineligible***. ☐1 Yes ☐0 No

   2b. Does this condition require you to regularly take steroid pills or injections? ***If YES, ineligible***. ☐1 Yes ☐0 No

Script: This next question is about drinking alcoholic beverages. Alcoholic beverages include beer, wine, wine coolers and liquor like whisky, vodka, or cocktails. A drink is one 12 ounce can of beer, a 5 ounce glass of wine or a drink containing a "shot", a "jigger" or a "finger of liquor".

3. During the past 12 months, how many drinks did you have in a typical week? Number of Drinks _____

   If you are unsure, please make your best estimate.

   If number of drinks > 21 per week, then ineligible.

4. Have you used drugs other than those prescribed by a physician or purchased in a pharmacy or store? ☐1 Yes ☐0 No
If YES, answer question 4a. If NO, skip to question 5.

   4a. What were they (check all that apply)?
   - ☐ Marijuana
   - ☐ Heroin or other opiods
   - ☐ Cocaine or other stimulants
   - ☐ Other, specify:_____

   If any of the above were selected, answer question 4b.

   4b. How long ago were they used?
   - ☐1 Within the past year ***If within the past year, then ineligible.***
   - ☐2 Longer than 1 year

5. Since the age of 60, have you seen a doctor for emotional, nervous, or psychiatric problems? **If YES, answer questions 5a, 5b and 5c.** ☐1 Yes ☐0 No

   5a. Were you seen for bipolar disease? ***If YES, ineligible*.** ☐1 Yes ☐0 No

   5b. Were you seen for schizophrenia? ***If YES, ineligible***. ☐1 Yes ☐0 No

   5c. Were you seen for depression? ☐1 Yes ☐0 No
   If YES, answer questions 5d and 5e.

   5d. Was this depression diagnosed within the past 3 months? ☐1 Yes ☐0 No
   If YES, need review by medical team for eligibility.

   5e. Were you seen for some other problem? ☐1 Yes ☐0 No

   Specify _____

   If YES, need review by medical team for eligibility.

6. Are you currently being treated for a skin condition such as psoriasis or eczema? **If YES, describe on question 6a.** ☐1 Yes ☐0 No

6a. Describe skin condition at the application site: ☐1 Normal ☐2 Abnormal

If ABNORMAL, describe: _____

If ABNORMAL, need review by medical team for eligibility.

6a1. ***Determination upon review by medical team?***
☐1 Eligible to continue
☐0 Ineligible to continue

6b. Do you have an allergy or intolerance to alcohol applied to the skin? ☐1 Yes ☐0 No

1. Has a doctor ever told you that you have high blood pressure or hypertension? **If YES, answer question 1a.** ☐1 Yes ☐0 No

   1a. Are you currently taking any medication for your high blood pressure? ☐1 Yes ☐0 No

2. Has a doctor ever told you that you had a heart attack, or coronary, or myocardial infarction for which you had to be hospitalized overnight? **If YES, answer question 2a.** ☐1 Yes ☐0 No

   2a. Was the heart attack in the previous 3 months? ☐1 Yes ☐0 No

   If YES, participant is ineligible

   2b. Do you have angina or chest pain due to heart disease that is not controlled by treatment? ☐1 Yes ☐0 No

   If YES, participant is ineligible

3. Has a doctor ever told you that you had a stroke or brain hemorrhage for which you had to be hospitalized overnight? **If YES, answer question 3a and 3b.** ☐1 Yes ☐0 No

   3a. Does this condition prevent you from walking a quarter mile? ☐1 Yes ☐0 No

   If YES, not eligible for physical function trial

   3b. Did the stroke take place in the previous 3 months? ☐1 Yes ☐0 No

   If YES, the participant is ineligible.

4. Has a doctor ever told you that you have diabetes, sugar in your urine, or high blood sugar? **If YES, answer question 4a and 4b.** ☐1 Yes ☐0 No

   4a. Are you now using medication to treat or control your diabetes? ☐1 Yes ☐0 No

   4b. How long have you had diabetes? __ __ Years ☐1 Less than a year

   If greater than 10 Years, answer question 4c.

   4c. Has your diabetes affected the circulation in your feet or sensation in your feet? ***If YES, requires review by medical team.*** ☐1 Yes ☐0 No

5. Has a primary health care physician or other health care provider ever diagnosed you with autonomic neuropathy? ☐1 Yes ☐0 No

   If YES, not eligible for sexual function trial

6. Has a doctor ever told you that you had a broken hip for which you had to be hospitalized? ☐1 Yes ☐0 No

7. Has a doctor ever told you that you have cirrhosis or liver disease? ☐1 Yes ☐0 No

8. During the last 6 months, have you seen a doctor specifically for arthritis or rheumatism? **If YES, answer question 8a.** ☐1 Yes ☐0 No

   8a. Does this condition prevent you from walking a quarter mile? ☐1 Yes ☐0 No

   If YES, not eligible for physical function trial

9. Do you have Parkinson's disease? **If YES, answer question 9a.** ☐1 Yes ☐0 No

   9a. Does your Parkinson's disease prevent you from walking a quarter mile? ☐1 Yes ☐0 No

   If YES, not eligible for physical function trial

10. Do you have some other serious neurological disorder? **If Yes, answer question 10a and 10b.** ☐1 Yes ☐0 No

    (Note to Interviewer: *DOES NOT include stroke).*

    10a. Other neurological disorder, specify:

    _____

    10b. Does your other neurological disorder prevent you from walking a quarter mile? ☐1 Yes ☐0 No

    If YES, not eligible for physical function trial

11. Do you have any medical or nonmedical problems that prevent you from having sex? ☐1 Yes ☐0 No

    (Examples include penile deformity, Peyronie's disease, pelvic surgery for bladder cancer)

    If YES, not eligible for sexual function trial

12. Other than the hospitalizations you have already told me about, have you been hospitalized for any other reason in the past year? ☐1 Yes ☐0 No
    If YES, specify in question 12a.

    12a. Specify: _____

    _____

    _____

13. Do you have any other medical conditions? ☐1 Yes ☐0 No
    If YES, specify in question 13a.

    13a. Specify: _____

    _____

    _____

14. Has the participant been diagnosed with any of the following:

    14a. Pituitary disease (eg pituitary adenoma, hypophysitis) ☐1 Yes ☐0 No

    14b. Hypothalamic disease (eg craniopharyngioma) or ☐1 Yes ☐0 No

    14c. Testicular disease (eg Kleinfelter's Syndrome, orchiectomy) ☐1 Yes ☐0 No

    If question 14a, 14b or 14c is YES, the participant is ineligible.

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL**	PID: __ __ __ __ __ __
	Myocardial Infarction Review Form	Site: __ __
		Date: __ __/__ __/ __ __ __ __

1. Reviewed by: ❑1 Mohler ❑2 Bild ❑3 Lewis ❑98 Other _____
2. Date event reviewed: __ __ / __ __ / __ __ __ __ (*mm/dd/yyyy*)
3. AE#: _____

Please base your review on the documentation provided from this investigation.

4. Is at least one Troponin value available? ❑1 Yes ***(go to Q#5)*** ❑0 No ***(go to Q#10)***

5. Select the Troponin I threshold: ***(check only one)***
   - ❑1 No Troponin I values available ***(go to Q#7)***
   - ❑2 Cannot determine the type of Troponin ***(go to Q#8)***
   - ❑3 0.14 - No ULN available ***(go to Q#6)***
   - ❑4 0.14 – Lab provides only a normal range and no indeterminate range and the ULN is ≥ 0.14. ***(go to Q#6)***
   - ❑5 If the lab provides only a normal range and no indeterminate range and the ULN is < 0.14. Record threshold.
     Specify: 2x ULN = ___.___ ___ ***(go to Q#6)***
   - ❑6 If the lab provides an indeterminate category in addition to a normal range. Record threshold.
     Specify: 2x ULN = ___.___ ___ ***(go to Q#6)***
   - ❑7 Record highest Troponin I value ___ ___.___ ___

6. Select the Troponin I Determination: ***(check only one)***
   - ❑1 Two or more values (~6 hours apart) ≤ ULN and < threshold = **normal.**
   - ❑2 Any value ≥ threshold = **abnormal**
   - ❑3 Only one value available < ULN = **normal**
   - ❑4 One or more value and all > ULN and < threshold = **equivocal**.

7. Select the Troponin T Determination: ***(check only one)***
   - ❑1 Any Troponin T ≤ 0.03 = **normal**
   - ❑2 Any Troponin T > 0.03 = **abnormal**
   - ❑3 No Troponin T
   - ❑4 Record highest Troponin I value ___ ___.___ ___

8. Select the Indeterminate Troponin: ***(check only one)***
   - ❑1 Any Troponin ≤ ULN = **normal**.
   - ❑2 Any Troponin ≥ 2x ULN = **abnormal**.
   - ❑3 Any Troponin >ULN < 2x ULN = **equivocal**.
   - ❑4 Record highest Troponin I value ___ ___.___ ___
   - ❑99 Not Applicable

9. Was there evidence of nonischemic cause of Troponin elevation (e.g., CPR, heart failure, CKD, etc). ❑$_1$ Yes ❑$_0$ No

10. Guidance for interpreting CK results ***(check only one and go to Q#11)***

	No Muscle Trauma	**Muscle Trauma**
MB-ULN Available, CK-MB Measured		
CK-MB > 99th percentile of ULN or if not available, > 2x ULN	❑$_1$ Abnormal	❑$_2$ Equivocal
CK-MB < 99th percentile of ULN or if not available, ≤ 2x ULN	❑$_3$ Normal	❑$_4$ Normal
No MB ULN Available, CK-MB Measured		
CK-MB ≥ 10% CKTOT	❑$_5$ Abnormal	❑$_6$ Equivocal
CK-MB ≥ 5% and <10% CKTOT	❑$_7$ Equivocal	❑$_8$ Equivocal
CK-MB <5% CKTOT	❑$_9$ Normal	❑$_{10}$ Normal
No CK-MB measured, CKTOT measured		
CKTOT ≥ 2x ULN	❑$_{11}$ Abnormal	❑$_{12}$ Equivocal
[(CKTOT>ULN **and** < 2x ULN)	❑$_{13}$ Equivocal	❑$_{14}$ Equivocal
[CKTOT>2x ULN	❑$_{15}$ Equivocal	❑$_{16}$ Equivocal
[(CKTOT<2x ULN **and** > ULN)	❑$_{17}$ Equivocal	❑$_{18}$ Equivocal
[CKTOT<ULN	❑$_{19}$ Normal	❑$_{20}$ Normal
[(CKTOT<2x ULN **and** >ULN)	❑$_{21}$ Normal	❑$_{22}$ Normal
CKTOT<ULN	❑$_{23}$ Normal	❑$_{24}$ Normal
No CK-MB measured, No CKTOT measured		
CKTOT ≥ 2x ULN	❑$_{25}$ Equivocal	❑$_{26}$ Equivocal
CKTOT <2x ULN	❑$_{27}$ Normal	❑$_{28}$ Normal
No CK-MB measured, No CKTOT, LDH measured		
LDH ≥ 2x ULN	❑$_{29}$ Equivocal	❑$_{30}$ Equivocal
LDH <2x ULN	❑$_{31}$ Normal	❑$_{32}$ Normal
No CK-MB measured, No CKTOT or LDH measured		
	❑$_{33}$ Missing	❑$_{34}$ Missing

11. Is at least one ECG available? ❑1 Yes ***(go to Q#12)*** ❑0 No ***(go to Q#13***)

12. ECG is ***(check only one)***
    - ❑1 Evolving
    - ❑2 Positive
    - ❑3 Nonspecific
    - ❑4 Negative, normal, uncodeable, other

13. Was cardiac pain present? ❑1 Yes ***(go to Q#14)*** ❑0 No ***(go to Q#15***) ❑88 Uncertain ***(go to Q#15)***

14. Guidance for myocardial infarction determination based on ECG data, cardiac biomarkers and **cardiac pain** documentation: ***(check only one and go to Q#16)***

CARDIAC PAIN	**Cardiac Biomarkers Classification**			
ECG Pattern	**Abnormal**	**Equivocal**	**Missing**	**Normal**
Diagnostic ECG (Evolution of major Q-wave)	❑1 Definite MI	❑2 Definite MI	❑3 Definite MI	❑4 Definite MI
Positive ECG (Evolution of ST Elevation with or without Q-wave **OR** new LBBB)	❑5 Definite MI	❑6 Probable MI	❑7 Probable MI	❑8 No MI
Non-Specific ECG (Evolution of ST-T Depression/inversion alone **OR** evolution of minor Q-waves alone)	❑9 Definite MI	❑10 Possible MI	❑11 No MI	❑12 No MI
ECG Negative for Ischemia Normal, Absent, Uncodable, or Other	❑13 Definite MI	❑14 Possible MI	❑15 No MI	❑16 No MI

15. Guidance for myocardial infarction determination based on ECG data, cardiac biomarkers and **absence of cardiac pain** documentation: ***(check only one and go to Q#16)***

***NO* CARDIAC PAIN**	**Cardiac Biomarkers Classification**			
ECG Pattern	**Abnormal**	**Equivocal**	**Missing**	**Normal**
Diagnostic ECG (Evolution of major Q-wave)	❑1 Definite MI	❑2 Definite MI	❑3 Definite MI	❑4 Definite MI
Positive ECG* (Evolution of ST Elevation with or without Q-wave **OR** new LBBB)	❑5 Definite MI	❑6 Probable MI	❑7 Possible MI	❑8 No MI
Non-Specific ECG (Evolution of ST-T Depression/inversion alone **OR** evolution of minor Q-waves alone)	❑9 Definite MI	❑10 Possible MI	❑11 No MI	❑12 No MI
ECG Negative for Ischemia Normal, Absent, Uncodable, or Other	❑13 Definite MI	❑14 No MI	❑15 No MI	❑16 No MI

16. What is your global impression of the final outcome using all available information in this medical record?
❑$_1$ No MI ❑$_3$ Probable MI ❑$_{88}$ Can't Determine
❑$_2$ Possible MI ❑$_4$ Definite MI

17. What was the participant's vital status at the discharge?
❑$_1$ Alive ❑$_{88}$ Unknown
❑$_2$ Dead

*These responses must be concordant with the responses of the 2nd reviewer.

18. Did the patient undergo coronary revascularization? ❑$_1$ Yes ❑$_0$ No →***(Finished)***
a. If **"Yes"** ***(check only one answer)***
❑$_1$ Coronary angioplasty (including angioplasty with stenting, atherectomy)
❑$_2$ Coronary artery bypass graft
❑$_{98}$ Other (Specify: _____)

b. Were cardiac biomarkers (Troponin or CK obtained? ***(check all that apply)***
❑$_1$ Before procedure
❑$_2$ After procedure

Comments:

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

***NOTE**: This form must be completed when the appointment window has closed and the visit did not occur (unless a Completion Form has been filed for the patient).*

1. Reason this visit was missed? (check all that apply)

- ☐ Unable to contact patient
- ☐ Patient refused to return
- ☐ Patient illness
- ☐ Family member illness
- ☐ Transportation problem
- ☐ Clinic error
- ☐ Scheduling difficulties
- ☐ Temporarily out of area
- ☐ Other _____

2. Has a new appointment been scheduled? ☐$_1$ Yes ☐$_0$ No

2a. If No,
explain:_____

Instructions: Words in boldface type should be read aloud clearly and slowly to the examinee. Item substitutions appear in parentheses. Administration should be conducted privately and in the examinee's primary language. Check 0 if the response is incorrect, or 1 if the response is correct. Begin by asking the following two questions:

1. **Do you have any trouble with your memory?** ☐$_1$ Yes ☐$_0$ No
2. **May I ask you some questions about your memory?** ☐$_1$ Yes ☐$_0$ No

3. Orientation To Time

a.	**What is the year?**	_____	☐ 0 ☐1
b.	**What is the season?**	_____	☐ 0 ☐1
c.	**What is the month or the year?**	_____	☐ 0 ☐1
d.	**What is the day of week?**	_____	☐ 0 ☐1
e.	**What is the date?**	_____	☐ 0 ☐1

4. Orientation To Place*****

a.	**Where are we now?**	_____	☐ 0 ☐1
b.	**What is the state** (province)?	_____	☐ 0 ☐1
c.	**What is the county** (or city/town)?	_____	☐ 0 ☐1
d.	**What is the city/town** (or part of city/neighborhood)?	_____	☐ 0 ☐1
e.	**What is the building** (room number or address)?	_____	☐ 0 ☐1

*Alternative place words that are appropriate for the setting and increasingly precise may be substituted and noted.

5. Registration*****

Listen carefully. I am going to say three words. You say them back after I stop. Ready? Here they are…APPLE *[pause]***, PENNY** *[pause],* **TABLE** *[pause].* **Now repeat those words back to me.**

[Repeat up to 5 times, but score only the first trial.]

a.	Apple	_____	☐ 0 ☐1
b.	Penny	_____	☐ 0 ☐1
c.	Table	_____	☐ 0 ☐1

Now keep those words in mind. I am going to ask you to say them again in a few minutes.

*Alternative word sets (e.g. PONY, QUARTER, ORANGE) may be substituted and noted when retesting an examinee.

6. Attention and Calculation [Series 7] *

Now I'd like you to subtract 7 from 100. Then keep subtracting 7 from each answer until I tell you to stop.

a. **What is 100 take away 7?** [93] _____ ☐ 0 ☐1
b. If needed, say: **Keep going.** [86] _____ ☐ 0 ☐1
c. If needed, say: **Keep going.** [79] _____ ☐ 0 ☐1
d. If needed, say: **Keep going.** [72] _____ ☐ 0 ☐1
e. If needed, say: **Keep going.** [65] _____ ☐ 0 ☐1

* Alternative item (WORLD backward) should only be administered if the examinee refuses to perform the Serial 7s task.

Substitute and score this item only if the examinee refuses to perform the Serial 7s task.

g. **Spell WORLD forward, then backward.**

Correct forward spelling if misspelled, but score only the backward spelling.

(D=1)	(L=1)	(R=1)	(O=1)	(W=1)	(0 to 5)
_____	_____	_____	_____	_____	_____

7. Recall

What are those three words I asked you to remember? *[Do not offer any hints.]*

a. Apple _____ ☐ 0 ☐1
b. Penny _____ ☐ 0 ☐1
c. Table _____ ☐ 0 ☐1

8. Naming *****

a. **What is this**? [Point to a pencil or pen.] _____ ☐ 0 ☐1
b. **What is this?** [Point to a watch.] _____ ☐ 0 ☐1

*Alternative common objects (e.g. eyeglasses, chair, keys) may be substituted and noted.

9. Repetition

Now I am going to ask you to repeat what I say. Ready? "NO IFS, ANDS, OR BUTS," Now say that.

[Repeat up to 5 times, but score only the first trial.]

a. NO IFS, ANDS, OR BUTS. _____ ☐ 0 ☐1

Detach the next page along the lengthwise perforation, and then tear it in half along the horizontal perforation. Use the upper half of the page (blank) for the Comprehension, Writing, and Drawing items that follow. Use the lower half of the page as a stimulus form for Reading ("CLOSE YOUR EYES") and Drawing (intersecting pentagons) items.

10. Comprehension

Listen carefully because I am going to ask you to do something. Take this paper in your right hand [pause], **fold it in half** [pause]**, and put it on the floor (**or **table).**

a. Take in right hand	☐ 0	☐1
b. Fold in half	☐ 0	☐1
c. Put on floor (or table)	☐ 0	☐1

11. Reading

Please read this and do what it says. [Show examinee the words on the stimulus form.]

a. Close your eyes	☐ 0	☐1

12. Writing

Please write a sentence. *[If examinee does not respond, say*: **Write about the weather.**] Place the blank piece of paper (unfolded) in front of the examinee and provide a pen or pencil. Score 1 point if the sentence is comprehensible and contains a subject and a verb. Ignore errors in grammar or spelling. ☐ 0 ☐1

13. Drawing

Please copy this design *[Display the intersecting pentagons on the stimulus form.]* Score 1 point if the drawing consists of two 5-sided figures that intersect to form a 4-sided figure. ☐ 0 ☐1

14. Total Score (Sum all item scores) _____ (30 points max.)
(Calculated by DMS)

15. Assessment of level of consciousness:

☐$_1$ Alert / Responsive

☐$_2$ Drowsy

☐$_3$ Stuporous

☐$_4$ Comatose/ Unresponsive

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Positive and Negative Affects Scale** Visit __ __ (Participant Completed via IVR)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

This scale consists of a number of words that describe different feelings and emotions. Read each item and then circle the appropriate number next to that word. Thinking about yourself and how you normally feel, indicate to what extent you have felt this way during the past week.

Use the following scale to record your answers.

	Very slightly or not at all	**A little**	**Moderately**	**Quite a bit**	**Extremely**
1. Upset	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2. Hostile	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. Alert	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4. Ashamed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. Inspired	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. Nervous	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7. Determined	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. Attentive	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9. Afraid	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10. Active	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

		Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
1a.	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
1b.	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
1c.	Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
1d.	Climbing several flights or stairs	☐ 1	☐ 2	☐ 3
1e.	Climbing one flight of stairs	☐ 1	☐ 2	☐ 3
1f.	Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
1g.	Walking more than a mile	☐ 1	☐ 2	☐ 3
1h.	Walking several hundred yards	☐ 1	☐ 2	☐ 3
1i.	Walking one hundred yards	☐ 1	☐ 2	☐ 3
1j.	Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

1. In general over the last week, my memory has been:

☐1 Excellent
☐2 Very good
☐3 Good
☐4 Fair
☐5 Poor

1. In general over the last week, my memory has been:

- ☐ 1 Excellent
- ☐ 2 Very good
- ☐ 3 Good
- ☐ 4 Fair
- ☐ 5 Poor

2. Since the start of the study, my overall memory is:

- ☐ 1 Very much better
- ☐ 2 Much better
- ☐ 3 A little better
- ☐ 4 No change
- ☐ 5 A little worse
- ☐ 6 Much worse
- ☐ 7 Very much worse

1. In general over the last week, my overall health status has been:

☐1 Excellent
☐2 Very good
☐3 Good
☐4 Fair
☐5 Poor

1. In general over the last week, my overall health status has been:

☐1 Excellent
☐2 Very good
☐3 Good
☐4 Fair
☐5 Poor

2. Since the start of the study, my overall health status is:

☐1 Very much better
☐2 Much better
☐3 A little better
☐4 No change
☐5 A little worse
☐6 Much worse
☐7 Very much worse

1. In general over the last week, my walking ability has been:

☐1 Excellent
☐2 Very good
☐3 Good
☐4 Fair
☐5 Poor

1. In general over the last week, my walking ability has been:

- ☐ 1 Excellent
- ☐ 2 Very good
- ☐ 3 Good
- ☐ 4 Fair
- ☐ 5 Poor

2. Since the start of the study, my overall ability to walk is:

- ☐ 1 Very much better
- ☐ 2 Much better
- ☐ 3 A little better
- ☐ 4 No change
- ☐ 5 A little worse
- ☐ 6 Much worse
- ☐ 7 Very much worse

1. In general over the last week, my sexual desire has been:

☐1 Excellent
☐2 Very good
☐3 Good
☐4 Fair
☐5 Poor

1. In general over the last week, my sexual desire has been:

☐1 Excellent
☐2 Very good
☐3 Good
☐4 Fair
☐5 Poor

2. Since the start of the study, my overall sexual desire is:

☐1 Very much better
☐2 Much better
☐3 A little better
☐4 No change
☐5 A little worse
☐6 Much worse
☐7 Very much worse

1. In general over the last week, my energy level has been:

☐1 Excellent
☐2 Very good
☐3 Good
☐4 Fair
☐5 Poor

1. In general over the last week, my energy level has been:

☐1 Excellent
☐2 Very good
☐3 Good
☐4 Fair
☐5 Poor

2. Since the start of the study, my overall energy level is:

☐1 Very much better
☐2 Much better
☐3 A little better
☐4 No change
☐5 A little worse
☐6 Much worse
☐7 Very much worse

Over the last 2 weeks, how often have you been bothered by any of the following problems?

		Not at all	Several Days	More than half the days	Nearly every day
1.	Little interest or pleasure in doing things	☐0	☐1	☐2	☐3
2.	Feeling down, depressed, or hopeless	☐0	☐1	☐2	☐3
3.	Trouble falling or staying asleep, or sleeping too much	☐0	☐1	☐2	☐3
4.	Feeling tired or having little energy	☐0	☐1	☐2	☐3
5.	Poor appetite or overeating	☐0	☐1	☐2	☐3
6.	Feeling bad about yourself - or that you are a failure or have let yourself or your family down	☐0	☐1	☐2	☐3
7.	Trouble concentrating on things, such as reading the newspaper or watching television	☐0	☐1	☐2	☐3
8.	Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	☐0	☐1	☐2	☐3
9.	Thoughts that you would be better off dead, or of hurting yourself in some way	☐0	☐1	☐2	☐3

10. Total PHQ-9 Score
(Calculated by DMS. If > 14, participant is ineligible) ----------

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Pre-existing Medical Conditions** (Research Coordinator Completed at Baseline Visit)	Participant ID:__ __ __ __ __ __ Participant Initials: __ __ __ Site: __ __

	Complete this from at the baseline visit only and use it at each subsequent visit and phone call to collect adverse event data with regard to changes (worsening) in pre-existing medical conditions.		**Record month & year.** **If unknown, record year only.**
Sequence Number	**Event**	**Description**	**Start Date (MM/YYYY)**
1			__ __/__ __ __ __
2			__ __/__ __ __ __
3			__ __/__ __ __ __
4			__ __/__ __ __ __
5			__ __/__ __ __ __
6			__ __/__ __ __ __
7			__ __/__ __ __ __
8			__ __/__ __ __ __
9			__ __/__ __ __ __
10			__ __/__ __ __ __

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL**	Participant ID:__ __ __ __ __ __
	PROCEDURE INVESTIGATION	Participant Initials __ __ __
	ADMINISTRATIVE CRF	Site: __ __
	(Research Coordinator Completed)	Date:__ __ / __ __ / __ __ __ __

1. DMS tracking number:

   ___ ___ ___

Note: Complete a separate Procedure Investigation (PROINVEST) form for each event that is indicated in the Event Notification generated by the DMS.

2. Cardiovascular Events Questionnaire (***CVEVENTS***) form date:

   __ __ / __ __ / __ __ __ __ (*mm/dd/yyyy*)

3. Indicate which of the following ambulatory procedures is being investigated:
   (Check ONE procedure per tracking number)

   3a. ☐ Echocardiography

   3b. ☐ Cardiac stress test (such as exercise stress test, MIBI, pMIBI, stress thallium, stress ECHO, dobutamine ECHO)

   3c. ☐ Head CT or MRI

   3d. ☐ Holter monitor (ECG)

---

4. Procedure investigation summary:

   ☐$_1$ Unable to document that the procedure occurred [STOP]

   ☐$_2$ Able to document that the test/procedure occurred
   [Obtain, copy and de-identify the ambulatory records and transfer them to the DCC.]

   ☐$_3$ This is a duplicate investigation of: Visit #: __ __; DMS tracking # __ __ __ [STOP]

Note: Complete the document checklist to indicate test result/records acquired.

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Pre- Screen** (Research Coordinator Completed)	Screening ID: __ __ __ __ __ __ Site: __ __ Date: __ __/__ __/ __ __ __ __

1. ***Do I have your permission to collect and record this information?*** ☐1 Yes ☐0 No

2. How did you hear about the study?

☐1 Brochure (obtained via direct mail)
☐2 Brochure (obtained from a community organization, event, doctor's office, etc)
☐3 Magazine or Newspaper Article or Ad
☐4 Radio Ad Interview
☐5 Television Ad Interview
☐6 Internet Information or Ad
☐7 Friend or Family Member
☐8 New physical function brochure
☐98 Other, Specify:_____

3. Are you currently involved in any other drug or device study? ***If YES, participant is ineligible, do not proceed.*** ☐1 Yes ☐0 No

4. Are you 65 years of age of older? ☐1 Yes ☐0 No
If NO, participant is ineligible, do not proceed.

5. During the past month, how much difficulty have you had walking ¼ of a mile (about 3-4 city blocks) without the aid of another person or any special equipment?

☐1 No difficulty
☐2 A little difficulty
☐3 Some difficulty
☐4 A lot of difficulty
☐5 Unable to do it
☐6 Do not do it for reasons other than difficulty
☐99 Do not know, or refused to answer

5a. During the past month, how much difficulty have you had climbing one flight of stairs without the aid of another person or any special equipment?

☐1 No difficulty
☐2 A little difficulty
☐3 Some difficulty
☐4 A lot of difficulty
☐5 Unable to do it
☐6 Do not do it for reasons other than difficulty
☐99 Do not know, or refused to answer

Only participants that answer "a little difficulty," "some difficulty," "a lot of difficulty," or "unable to do it" to either question 5 or 5a are eligible for the Physical Function Trial.

6. Are you concerned that your energy is low? ☐1 Yes ☐0 No

7. Has your desire for sex decreased? ***If YES, answer question 7a.*** ☐1 Yes ☐0 No

7a. Do you have a sexual partner who is willing to have sexual intercourse two or more times a month? ***If NO, participant is not eligible for sexual function trial.*** ☐1 Yes ☐0 No

If Questions 5, 6 and 7 are ALL answered NO, participant is ineligible; do not proceed.

8a. Have you taken any medications that contain testosterone such as topical gel, transdermal patch, injections or pellets in the last 3 months or for 2 months within the past year? ☐1 Yes ☐0 No
If YES, participant is ineligible, do not proceed.

9.	Do you have a skin allergy or intolerance to topical gels which contain alcohol? ***If YES, participant is ineligible, do not proceed.***	☐1 Yes	☐0 No
10.	~~Have you been diagnosed with sleep apnea? ***If YES, answer question 10a.***~~	~~☐1 Yes~~	~~☐0 No~~
	10a. ~~Are you being treated for this condition? ***If NO, participant is ineligible, do not proceed.***~~	~~☐1 Yes~~	~~☐0 No~~
11.	Do you have a condition that requires you to wear oxygen throughout the day? ***If YES, participant is ineligible, do not proceed.***	☐1 Yes	☐0 No
12.	Do you have angina or chest pain due to heart disease that is not controlled by treatment? ***If YES, participant is ineligible, do not proceed.***	☐1 Yes	☐0 No
13.	Do you have severe kidney disease that requires dialysis? ***If YES, participant is ineligible, do not proceed.***	☐1 Yes	☐0 No
14.	What is your height?	__ __ inches	
15.	What is your weight?	__ __ __ . __ lbs	
16.	What is the participants BMI score? ***Use this website to verify the BMI score which will be calculated by the DMS upon saving this form:*** ***http://www.nhlbisupport.com/bmi/bmicalc.htm*** ***If BMI > 37, participant is ineligible, do not proceed.***	__ __ __ . __ __ ***(Calculated by DMS)***	
17.	Have you had a Heart Attack (Myocardial Infarction) in the past 3 months that required overnight hospitalization? ***If YES, participant is ineligible, do not proceed.***	☐1 Yes	☐0 No
18.	Within the past 6 months, have you had any of these conditions? ***If NO, skip to question 19.***		
	a. ☐ Major heart surgery, including valve replacement or bypass surgery	☐1 Yes	☐0 No
	b. ☐ Stroke or brain hemorrhage ***(Note: Does not include TIA)***	☐1 Yes	☐0 No
	c. ☐ Hip fracture	☐1 Yes	☐0 No
	d. ☐ Hip or knee replacement	☐1 Yes	☐0 No
	e. ☐ Spinal surgery	☐1 Yes	☐0 No
	f. ☐ Blood clot in your leg or in your lungs	☐1 Yes	☐0 No
	If participant answered YES to any conditions, participant is ineligible, do not proceed.		
19.	Have you ever been diagnosed with prostate cancer? ***If YES, participant is ineligible, do not proceed.***	☐1 Yes	☐0 No
	19a. Have you been diagnosed with prostatic intraepithelial neoplasia (PIN)? **If YES, *participant is ineligible, do not proceed.***	☐1 Yes	☐0 No

20. In the past 3 years, have you been treated for another type of cancer or been told by a doctor that you had another type of cancer or a malignant tumor? ☐1 Yes ☐0 No
***If YES, answer questions 20a and 20b*.**

20a. Please tell me what type of cancer you had:

☐ Leukemia/ Lymphoma ☐ Pancreas ☐ Head or Neck ☐ Thyroid

☐ Lung ☐ Colon/ Rectal ☐ Breast

☐ Bladder

☐ Other Cancers:_____

☐ ***Nonmelanoma Skin **** **** If participant has a nonmelanomic skin condition, review by medical team at SV1 for eligibility must be performed.***

20b. Are you currently receiving radiation treatment and/or chemotherapy for this cancer? ☐1 Yes ☐0 No
If YES, participant is ineligible, do not proceed.
If NO, review by medical team at SV1 for eligibility.

21. Is this participant eligible to proceed to Screening Visit 1? ☐1 Yes ☐0 No

22. The T-Trial has requirements that include the following activities: attending study visits, applying gel every day, a walking test, physical measurements, reading forms and answering questions. Do you have any medical conditions or physical limitations that would prevent you from fully participating in the trial? ☐1 Yes ☐0 No

22a. If YES, describe:_____

_____

23. Is this a re-screening? ☐1 Yes ☐0 No

If YES, answer 23a and 23b

23a. Participant ID of previous screening _____

23b Date of previous screening __ __/__ __/__ __ __ __

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Pre- Screen** (Research Coordinator Completed)	Screening ID: __ __ __ __ __ __ Site: __ __ Date: __ __/__ __/ __ __ __ __

1. ***Do I have your permission to collect and record this information?*** ☐1 Yes ☐0 No

2. How did you hear about the study?

☐1 Brochure (obtained via direct mail)
☐4 Radio Ad Interview
☐7 Friend or Family Member
☐2 Brochure (obtained from a community organization, event, doctor's office, etc)
☐5 Television Ad Interview
☐8 New physical function brochure
☐3 Magazine or Newspaper Article or Ad
☐6 Internet Information or Ad
☐98 Other, Specify:_____

3. Are you currently involved in any other drug or device study? ***If YES, participant is ineligible, do not proceed.*** ☐1 Yes ☐0 No

4. Are you 65 years of age of older? ☐1 Yes ☐0 No
If NO, participant is ineligible, do not proceed.

5. During the past month, how much difficulty have you had walking ¼ of a mile (about 3-4 city blocks) without the aid of another person or any special equipment?

☐1 No difficulty
☐4 A lot of difficulty
☐99 Do not know, or refused to answer
☐2 A little difficulty
☐5 Unable to do it
☐3 Some difficulty
☐6 Do not do it for reasons other than difficulty

5a. During the past month, how much difficulty have you had climbing one flight of stairs without the aid of another person or any special equipment?

☐1 No difficulty
☐4 A lot of difficulty
☐99 Do not know, or refused to answer
☐2 A little difficulty
☐5 Unable to do it
☐3 Some difficulty
☐6 Do not do it for reasons other than difficulty

Only participants that answer "a little difficulty," "some difficulty," "a lot of difficulty," or "unable to do it" to either question 5 or 5a are eligible for the Physical Function Trial.

6. Are you concerned that your energy is low? ☐1 Yes ☐0 No

7. Has your desire for sex decreased? ***If YES, answer question 7a.*** ☐1 Yes ☐0 No

7a. Do you have a sexual partner who is willing to have sexual intercourse two or more times a month? ***If NO, participant is not eligible for sexual function trial.*** ☐1 Yes ☐0 No

If Questions 5, 6 and 7 are ALL answered NO, participant is ineligible; do not proceed.

8a. Have you taken any medications that contain testosterone such as topical gel, transdermal patch, injections or pellets in the last 3 months or for 2 months within the past year? ☐1 Yes ☐0 No
If YES, participant is ineligible, do not proceed.

9.	Do you have a skin allergy or intolerance to topical gels which contain alcohol? ***If YES, participant is ineligible, do not proceed.***	☐1 Yes	☐0 No
10.	~~Have you been diagnosed with sleep apnea? ***If YES, answer question 10a.***~~	~~☐1 Yes~~	~~☐0 No~~
	10a. ~~Are you being treated for this condition? ***If NO, participant is ineligible, do not proceed.***~~	~~☐1 Yes~~	~~☐0 No~~
11.	Do you have a condition that requires you to wear oxygen throughout the day? ***If YES, participant is ineligible, do not proceed.***	☐1 Yes	☐0 No
12.	Do you have angina or chest pain due to heart disease that is not controlled by treatment? ***If YES, participant is ineligible, do not proceed.***	☐1 Yes	☐0 No
13.	Do you have severe kidney disease that requires dialysis? ***If YES, participant is ineligible, do not proceed.***	☐1 Yes	☐0 No
14.	What is your height?	__ __ inches	
15.	What is your weight?	__ __ __ . __ lbs	
16.	What is the participants BMI score? ***Use this website to verify the BMI score which will be calculated by the DMS upon saving this form:*** ***http://www.nhlbisupport.com/bmi/bmicalc.htm*** ***If BMI > 37, participant is ineligible, do not proceed.***	__ __ __ . __ __ ***(Calculated by DMS)***	
17.	Have you had a Heart Attack (Myocardial Infarction) in the past 3 months that required overnight hospitalization? ***If YES, participant is ineligible, do not proceed.***	☐1 Yes	☐0 No
18.	Within the past 6 months, have you had any of these conditions? ***If NO, skip to question 19.***		
	a. ☐ Major heart surgery, including valve replacement or bypass surgery	☐1 Yes	☐0 No
	b. ☐ Stroke or brain hemorrhage ***(Note: Does not include TIA)***	☐1 Yes	☐0 No
	c. ☐ Hip fracture	☐1 Yes	☐0 No
	d. ☐ Hip or knee replacement	☐1 Yes	☐0 No
	e. ☐ Spinal surgery	☐1 Yes	☐0 No
	f. ☐ Blood clot in your leg or in your lungs	☐1 Yes	☐0 No
	If participant answered YES to any conditions, participant is ineligible, do not proceed.		
19.	Have you ever been diagnosed with prostate cancer? ***If YES, participant is ineligible, do not proceed.***	☐1 Yes	☐0 No
	19a. Have you been diagnosed with prostatic intraepithelial neoplasia (PIN)? **If YES, *participant is ineligible, do not proceed.***	☐1 Yes	☐0 No

20. In the past 3 years, have you been treated for another type of cancer or been told by a doctor that you had another type of cancer or a malignant tumor? (With the exception of nonmelanotic skin cancers)? ☐1 Yes ☐0 No
IF YES, participant is ineligible, do not proceed.

The following shaded section is archived and no longer needs to be asked at pre-screening.

20a. Please tell me what type of cancer you had:

☐ Leukemia/ Lymphoma ☐ Pancreas ☐ Head or Neck ☐ Thyroid

☐ Lung ☐ Colon/ Rectal ☐ Breast

☐ Bladder

☐ Other Cancers:_____

☐ ***Nonmelanoma Skin **** **** If participant has a nonmelanomic skin condition, review by medical team at SV1 for eligibility must be performed.***

20b. Are you currently receiving radiation treatment and/or chemotherapy for this cancer? ☐1 Yes ☐0 No
If YES, participant is ineligible, do not proceed.
If NO, review by medical team at SV1 for eligibility.

21. Is this participant eligible to proceed to Screening Visit 1? ☐1 Yes ☐0 No

22. The T-Trial has requirements that include the following activities: attending study visits, applying gel every day, a walking test, physical measurements, reading forms and answering questions. Do you have any medical conditions or physical limitations that would prevent you from fully participating in the trial? ☐1 Yes ☐0 No

22a. If YES, describe:_____

_____

23. Is this a re-screening? ☐1 Yes ☐0 No

If YES, answer 23a and 23b

23a. Participant ID of previous screening _____

23b Date of previous screening __ __/__ __/__ __ __ __

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:__ __ / __ __ / __ __ __ __

QCT Scan

PLEASE NOTE FOR MONTH 12 SCANS:

The month 12 QCT scan must be performed using the same CT scanner, same pre-programmed (TTrial) protocol, and same table height as used for the baseline scan.

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

   If YES:

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

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: _____

2. 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** **Randomization** Baseline (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

RESEARCH COORDINATOR AND PRINCIPAL INVESTIGATOR COMPLETE THIS FORM TO RANDOMIZE THE PARTICIPANT

1. The participant has met all eligibility criteria and the PI has reviewed and certified individual as being eligible: ☐1 Yes ☐0 No

2. The participant is eligible and has agreed to participate in:
   - Physical Function Trial ☐1 Yes ☐0 No
   - Sexual Function Trial ☐1 Yes ☐0 No
   - Vitality Function Trial ☐1 Yes ☐0 No

3. Did participant give permission to use their sample(s) [DNA, RNA, cell lines] as described below?
   - Researchers studying testosterone levels and their response to treatment ☐1 Yes ☐0 No
   - Researchers studying other diseases (for example, cancer or arthritis) ☐1 Yes ☐0 No

4. Did participant give permission to share information included in a national GWAS database?
   - Include participant information in the GWAS database. ☐1 Yes ☐0 No
   - *If yes, information can be released from the GWAS database to:*
   - Researchers studying testosterone-related disease ☐1 Yes ☐0 No
   - Researchers studying any disease ☐1 Yes ☐0 No

5. Did participant consent to have their primary care physician contacted for follow up of symptoms? ☐1 Yes ☐0 No

6. Did participant consent to have their social security number collected? ☐1 Yes ☐0 No

7. Date of Randomization: __ __ / __ __ / __ __ __ __ (mm / dd / yyyy)

8. Study Randomization Message and Kit Number assignment: __ __ __ __

9. Cognitive Function Packet Randomization Message and assignment: __ __ __

Investigator's Statement

I have reviewed the eligibility information for this participant and certify that, to the best of my knowledge, this individual has met all eligibility requirements for enrollment in this study as described in the protocol.

10. Signature of Investigator: _____ __ __ / __ __ / __ __ __ __ (mm / dd / yyyy)

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Reassessment of Eligibility** Visit __ __ (Completed by Research Coordinator)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Has the participant been consented for reassessment? ❑$_1$ Yes ❑$_0$ No
   a. If YES, date of consent __ __/__ __/__ __ __ __
      mm dd yyyy

Answers to the questions below only pertain to participants originally ineligible to a specific trial.

Based on changes to eligibility criteria…

2. Is the participant now eligible for the Physical Function Trial? ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ N/A
3. Is the participant now eligible for the Sexual Function Trial? ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ N/A
4. Is the participant now eligible for the Vitality Function Trial? ❑$_1$ Yes ❑$_0$ No ❑$_{99}$ N/A

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Reported Death Evaluation Form** (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Death of participant reported to T Trial Coordinator.
   Date:_____

2. Did you conduct an informant interview?
   ☐$_1$ Yes ☐$_0$ No

Comments: _____

If "Yes" continue. If "No" stop.

Complete this section based on informant interview.

3. Indicate the category that best characterizes this informant:
   ☐$_1$ Spouse
   ☐$_2$ Child
   ☐$_3$ Other relative
   ☐$_4$ Friend
   ☐$_5$ Neighbor
   ☐$_{98}$ Other _____

4. Where did [*Participant Name*] die?
   ☐$_1$ Home
   ☐$_2$ Hospital/Emergency Department
   ☐$_3$ Nursing home/other skilled nursing facility
   ☐$_4$ Hospice
   ☐$_{88}$ Don't know
   ☐$_{98}$ Other: _____

If [Participant Name] died in a hospital or other health care facility, please indicate the name and address of this facility (if known)?

(This information should NOT be entered into the DMS)

Name: _____

Address: _____

_____

_____

5. What was the cause of death (if known)?
   ☐$_1$ Cardiovascular event (heart attack, heart failure or other heart related problem)
   ☐$_2$ Cerebrovascular event (stroke)
   ☐$_{88}$ Don't know
   ☐ Unknown
   ☐$_{98}$ Other

6. Evaluation Summary:
   ☐$_1$ Participant's death occurred in the hospital or emergency department
   [Obtain, copy, and de-identify death certificates, autopsy/coroner's reports, obituaries or relevant hospital records and transfer them to the to DCC.]
   ☐$_2$ Participant's death occurred outside of the hospital or emergency department
   [Obtain, copy and de-identify any death certificates, autopsy/coroner's reports, or obituaries and transfer them to the DCC.]

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Gel Resupply Request**	Participant ID: __ __ __ __ __ __ Participant Initials: __ __ __ Site: __ __

1. What Kit number was dispensed to the participant? __ __ __ __

1a. Date of Randomization: __ __ / __ __ / __ __ __ __

2. Indicate the type of resupply:
☐1 Standard Resupply
☐2 Dose Adjusted Resupply

2a. If Dose Adjusted Resupply, indicate the number of bottles. __ __
(Reference Estimated Dose Chart below)

Estimated Dose Chart
2.5gm/day (2 depressions/day) - 30 days per bottle (**4** bottles for 3 months)
5gm/day (4 depressions/day) - 15 days per bottle (**7** bottles for 3 months)
7.5gm/day (6 depressions/day) - 10 days per bottle (**10** bottles for 3 months)
10gm/day (8 depressions/day) - 7.5 days per bottle (**13** bottles for 3 months)

2b. If ***DOSE ADJUSTED RESUPPLY***, please complete the following:

Date of Most Recent Kit Distribution	***Previous Number of Depressions***	***Dose Change***	***Current Number of Depressions***
__ __ / __ __ / __ __ __ __	__ __	☐1 Increase Dose ☐2 Decrease Dose	__ __

Fax the completed Gel Resupply Request form to Ken Rockwell at the Investigational Drug Service.
Fax # (215) 349-5132

(INTERNAL USE ONLY)

Date Resupply Shipped: __ __ / __ __ / __ __ __ __

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Prostate Cancer Risk Calculator** Screening Visit 1 (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Research Coordinator completes questions 1-7

1. What is the participant's race?
   - ☐ 1 African American
   - ☐ 2 Caucasian
   - ☐ 3 Hispanic
   - ☐ 98 Other
2. What is the participant's age? __ __
3. Does the participant have a family history of Prostate Cancer?
   Choose "Yes" if a father, brother, or son had prostate cancer.
   ☐ 1 Yes ☐ 0 No
4. What are the participant's Digital Rectal Exam results?
   For the purposes of this form, <u>at this visit only</u>, the results of the DRE are assumed to be "Normal".
   ☐ 1 Normal ☐ 2 Abnormal
5. Has the participant had a prior prostate biopsy?
   - ☐ 1 Never had a biopsy
   - ☐ 2 Past negative biopsy
   - ☐ 3 Past positive biopsy
6. Is the participant currently taking Finasteride or Proscar?
   ☐ 1 Yes ☐ 0 No
7. Is the participant currently taking Dutasteride or Avodart?
   ☐ 1 Yes ☐ 0 No

Questions 8 and 9 are completed in data management system.

8. Participant status:
   - ☐ Eligible
   - ☐ Ineligible
   - ☐ Lab results pending after 2 weeks
9. Check box to confirm review of participant status. ☐ 1

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Screening Visit 1** (Research Coordinator Completed)	Participant ID: __ __ __ __ __ __ Participant Initials: __ __ __ Site: __ __ Date: __ __/ __ __/ __ __ __ __

1. Has the participant signed the Screening Informed Consent? ☐1 Yes ☐0 No

   a. If **YES**, Date of Consent: __ __/__ __/__ __ __ __ (MM DD YYYY)

2. Has blood been drawn? ☐1 Yes ☐0 No

   a. If **NO**, explain:_____

   b. If **YES**, what time was the blood drawn? __ __ : __ __ ☐1 AM ☐2 PM

   c. If **YES**, was participant fasting? ☐1 Yes ☐0 No

3. Does participant have a working touch-tone telephone for IVR use? ☐1 Yes ☐0 No

   a. If **NO**, was a touch-tone telephone provided? ☐1 Yes ☐0 No

Note: Ask the following questions, 4-8, to confirm the information reported at pre-screening.

4. What Screening ID Number was used for the participant's Pre-Screen Visit? __ __ __ __ __ __

5. <u>NOTE: The responses to questions 5 and 5a must be transcribed from the PRESCREEN form. Do NOT ask the participant these questions again.</u>

   During the past month, how much difficulty have you had walking ¼ of a mile (about 3-4 city blocks) without the aid of another person or any special equipment?

   ☐1 No difficulty
   ☐2 A little difficulty
   ☐3 Some difficulty
   ☐4 A lot of difficulty
   ☐5 Unable to do it
   ☐6 Do not do it for reasons other than difficulty
   ☐99 Do not know, or refused to answer

   5a. During the past month, how much difficulty have you had climbing one flight of stairs without the aid of another person or any special equipment?

   ☐1 No difficulty
   ☐2 A little difficulty
   ☐3 Some difficulty
   ☐4 A lot of difficulty
   ☐5 Unable to do it
   ☐6 Do not do it for reasons other than difficulty
   ☐99 Do not know, or refused to answer

Only participants that answer "a little difficulty," "some difficulty," "a lot of difficulty," or "unable to do it" to either question 5 or 5a are eligible for the Physical Function Trial.

6. Is the participant concerned that his energy is low? ☐1 Yes ☐0 No

If NO, not eligible for Vitality Trial.

7. Has the participant's desire for sex decreased? ☐1 Yes ☐0 No

   a. If **YES**, did the participant indicate if he had a sexual partner who was willing to have sexual intercourse two or more times a month? ☐1 Yes ☐0 No

If NO, not eligible for Sexual Function Trial.

8. Did the participant report being treated for cancer, or has the participant been told by a doctor he had cancer or a malignant tumor, within the past 3 years (With the exception of nonmelanotic skin cancers)? ☐1 Yes ☐0 No

If YES, not eligible for the trial

If **YES**, which of the following did they report they had?

☐ Leukemia / Lymphoma ☐ Pancreas ☐ Head or Neck ☐ Thyroid

☐ Lung ☐ Colon / Rectal ☐ Breast

☐ ***Bladder***
Surgery for Bladder Cancer?
☐1 Yes
☐0 No
Was this reviewed by medical team?
☐1 Yes – determined eligible to continue
☐0 No – determined ineligible

☐ ***Nonmelanoma Skin***
Was this reviewed by medical team?
☐1 Yes – determined eligible to continue
☐0 No – determined ineligible

☐ ***Other Cancers***: _____
_____
Was this reviewed by medical team?
☐1 Yes – determined eligible to continue
☐0 No – determined ineligible

Is the participant currently receiving radiation treatment and or chemotherapy for their cancer? ☐1 Yes ☐0 No

If **YES**, participant is ineligible.

If **NO**, was this reviewed by medical team?
☐1 Yes – determined eligible to continue
☐0 No – determined ineligible

9. Is participant eligible for screening visit 2? ☐1 Yes ☐0 No

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Screening Visit 1** **Eligibility Assessment** (Research Coordinator Completed)	Participant ID: __ __ __ __ __ __ Participant Initials: __ __ __ Site: __ __ Date: __ __/__ __/__ __ __ __

1a.	Have you ever been told by a doctor or health care provider that you have sleep apnea? **If NO, skip to question 2.** **If YES, use the Sleep Apnea Assessment Guidelines to determine the status of the sleep apnea diagnosis and treatment and answer question 1b.**	☐1 Yes	☐0 No
1b.	Assessment of sleep apnea indicates that participant is eligible to proceed to Screening Visit 2.	☐1 Yes	☐0 No
2.	Is participant being treated by dialysis? **(If YES, participant is NOT eligible.)**	☐1 Yes	☐0 No
3.	Does participant have creatinine > 2.2 mg/dl? **(If YES, participant is NOT eligible.)**	☐1 Yes	☐0 No
4.	Does participant have ALT 3X upper limit of normal? **(If YES, participant is NOT eligible.)**	☐1 Yes	☐0 No
5.	Has the participant taken drugs that affect serum testosterone concentration for more than 2 months during the previous 12 months, or within the previous three months? **(If YES, participant is NOT eligible.)** Examples of drugs: testosterone, androstenedione, DHEA, estrogens, GnRH analogs, spironolactone, and ketoconazole.	☐1 Yes	☐0 No
6.	Has the participant taken rhGH or megesterol acetate within the previous three months? **(If YES, participant is NOT eligible.)**	☐1 Yes	☐0 No
7.	Has the participant been introduced to any anti-depressant medications within the past three months? **(If YES, participant is NOT eligible.)** NOTE: Subjects with diagnosed depression who have been stable for more than three months while taking anti-depressant medication are eligible.	☐1 Yes	☐0 No
8.	Has the participant taken prednisone (dose of greater than 5 mg daily) daily for more than two weeks, or equivalent doses of other glucocorticoids for more than two weeks during the previous three months? **(If YES, participant is NOT eligible.)**	☐1 Yes	☐0 No
9.	Has the participant taken opiates within the past three months? **(If YES, participant is NOT eligible.)** Subjects who are using opiate analgesics intermittently for relief of chronic pain at doses that do not exceed the equivalent of 20 mg methadone daily will be included. The following doses of opiate analgesics are considered equivalent: ▪ Methadone 20 mg ▪ Hydrocodone 30 mg ▪ Oxycodone 30 mg ▪ Morphine sulfate 30 mg ▪ Codeine sulfate 200 mg	☐1 Yes	☐0 No
10.	Has the participant taken any antipsychotic medications for Axis I disorders? **(If YES, participant is NOT eligible.)**	☐1 Yes	☐0 No
11.	Are there reasons other than eligibility or screening criteria that the clinical site deems this participant ineligible to participate in the TTRIAL? 11a. If YES, specify reason(s): _____	☐1 Yes	☐0 No
12.	Is this a re-screening? **If YES, answer 12a and 12b** 12a. Participant ID of previous screening _____ 12b. Date of previous screening __ __/__ __/__ __ __ __	☐1 Yes	☐0 No

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Screening Visit 2** (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Did the participant bring their medications (including vitamins, minerals, and supplements) or a listing of their medications to be recorded for study purposes?

☐1 Yes ☐0 No

(If **YES**, update the Concomitant Medication Log)

2. Has blood been drawn?

☐1 Yes ☐0 No

If **NO,** explain**:**_____

If **YES**, what time was the blood drawn? __ __ : __ __ ☐1 AM ☐2 PM

If **YES**, was participant fasting? ☐1 Yes ☐0 No

3. Has a urine specimen been collected?

☐1 Yes ☐0 No

If **NO,** explain**:**_____

4. Was Digital Rectal Exam performed?

☐1 Yes ☐0 No

If **NO,** explain**:**_____

If **YES**, results: ☐1 Normal ☐2 Abnormal

If **ABNORMAL**, does the participant have a prostate nodule? ☐1 Yes ☐0 No

If YES, participant must be referred for evaluation.

4a. What is the size of the prostate?

☐1 Normal

☐2 Mildly enlarged

☐3 Moderately enlarged

☐4 Very enlarged

5. Has the participant used a PDE-5 inhibitor for erectile dysfunction within the past month? ☐$_1$ Yes ☐$_0$ No

If **YES**, indicate which PDE-5 Inhibitor was used:

☐ Viagra or Sildenafil

☐ Levitra or Vardenafil

☐ Cialis or Tadalafil

(If any of the above medications were used, also update the Concomitant Medication Log)

6. Were IVR forms and instructions provided? ☐$_1$ Yes ☐$_0$ No

7. Is participant eligible for baseline? ☐$_1$ Yes ☐$_0$ No

For each of the following questions, please select the appropriate response.

1. In general, would you say your health is:

   ☐1 Excellent
   ☐2 Very Good
   ☐3 Good
   ☐4 Fair
   ☐5 Poor

2. Compared to one year ago, how would you rate your health in general now?

   ☐1 Much better now than one year ago
   ☐2 Somewhat better now than one year ago
   ☐3 About the same as one year ago
   ☐4 Somewhat worse now than one year ago
   ☐5 Much worse now that one year ago

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐1	☐2	☐3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐1	☐2	☐3
c. Lifting or carrying groceries	☐1	☐2	☐3
d. Climbing several flights of stairs	☐1	☐2	☐3
e. Climbing one flight of stairs	☐1	☐2	☐3
f. Bending, kneeling, or stopping	☐1	☐2	☐3
g. Walking more than a mile	☐1	☐2	☐3
h. Walking several hundred yards	☐1	☐2	☐3
i. Walking one hundred yards	☐1	☐2	☐3
j. Bathing or dressing yourself	☐1	☐2	☐3

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	☐1	☐2	☐3	☐4	☐5
b. Accomplished less than you would like	☐1	☐2	☐3	☐4	☐5
c. Were limited in the kind of work or other activities	☐1	☐2	☐3	☐4	☐5
d. Had difficulty performing the work or other activities (for example, it took extra effort)	☐1	☐2	☐3	☐4	☐5

5 During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious).?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	☐1	☐2	☐3	☐4	☐5
b. Accomplished less than you would like	☐1	☐2	☐3	☐4	☐5
c. Did work or other activities less carefully than usual	☐1	☐2	☐3	☐4	☐5

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family friends, neighbors, or groups?

☐1 Not at all ☐2 Slightly ☐3 Moderately ☐4 Quite a Bit ☐5 Extremely

7. How much bodily pain have you had during the past 4 weeks?

☐1 None ☐2 Very Mild ☐3 Mild ☐4 Moderate ☐5 Severe ☐6 Very Severe

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐1 None ☐2 A little bit ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closet to the way you have been feeling.

How much of the time during the past 4 weeks….	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a. Did you feel full of life?	☐1	☐2	☐3	☐4	☐5
b. Have you been very nervous?	☐1	☐2	☐3	☐4	☐5
c. Have you felt so down in the dumps that nothing could cheer you up?	☐1	☐2	☐3	☐4	☐5
d. Have you felt calm and peaceful?	☐1	☐2	☐3	☐4	☐5
e. Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5
f. Have you felt downhearted and depressed?	☐1	☐2	☐3	☐4	☐5
g. Did you feel worn out?	☐1	☐2	☐3	☐4	☐5
h. Have you been happy?	☐1	☐2	☐3	☐4	☐5
i. Did you feel tired?	☐1	☐2	☐3	☐4	☐5

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)

	☐1	☐2	☐3	☐4	☐5

11. How TRUE or FALSE is each of the following statements for you?

	Definitely True	**Mostly True**	**Don't Know**	**Mostly False**	**Definitely False**
a. I seem to get sick a little easier than other people	☐1	☐2	☐3	☐4	☐5
b. I am healthy as anybody I know	☐1	☐2	☐3	☐4	☐5
c. I expect my health to get worse	☐1	☐2	☐3	☐4	☐5
d. My health is excellent	☐1	☐2	☐3	☐4	☐5

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **SF-36 Health Survey Vitality** Visit __ __ (Participant Completed via IVR)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closet to the way you have been feeling. How much of the time during the past 4 weeks….

		All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
1a.	Did you feel full of life?	☐1	☐2	☐3	☐4	☐5
1b.	Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5
1c.	Did you feel worn out?	☐1	☐2	☐3	☐4	☐5
1d.	Did you feel tired?	☐1	☐2	☐3	☐4	☐5

SLEEP APNEA ASSESSMENT GUIDELINE

Instructions: Ask the questions below to determine the status of the sleep apnea diagnosis and treatment. (Note: <u>These responses are NOT entered into the DMS but should be saved as source documentation of this assessment</u>.)

a. When was the diagnosis made? _____ years ago

b. Was the diagnosis made by polysomnography (PSG) testing in a sleep laboratory or at home during which your breathing patterns were measured? Yes or No

c. If no, how was the diagnosis made? _____

c.1. Was the condition: Mild - Moderate – Severe – Unknown?

d. Was treatment prescribed, such as -
- CPAP (a mask-like device that holds pressure in your lungs while you sleep)
- an oral appliance
- oxygen therapy
- oral surgery
- weight loss recommended

If *No*, to all of the above treatments, skip to question f.

e. If *Yes*, to any of the above treatments -
- Was your sleep apnea problem successfully treated in the past? Yes or No
  If *yes* to question e, skip to question h
- Is your sleep apnea problem now being successfully treated? Yes or No
  If *yes* to question e, skip to question h

f. Have you been prescribed treatment that you cannot use because of discomfort, or do not use because you think that it does not improve your sleep apnea?

Yes or No

If yes, skip to question h
If no, proceed to next question

g. Has it been determined by a health care provider that treatment of sleep apnea is no longer necessary? (For example, weight loss can significantly improve the problem of sleep apnea.)

Yes or No

h. Determine into which category the participant fits:

☐ Sleep apnea is mild and treatment (other than weight loss) has not been recommended– ELIGIBLE

☐ Sleep apnea is mild, moderate or severe and was successfully treated in the past – ELIGIBLE+ see below

☐ Sleep apnea is mild, moderate or severe and is successfully being treated at this time – ELIGIBLE+ see below

☐ Sleep apnea is a current health problem that is not currently being treated – NOT ELIGIBLE

i. Follow-up may be required before or at SV2 to assess treatment. Indicate the information that was provided to confirm the successful treatment of sleep apnea.

☐ PSG test results

☐ Treating and/or primary care physician confirmation (Verbal and/or written)

☐ Principal Investigator assessment of sleep history

☐ Other

j. During the past month, how often have you had trouble staying awake while driving, eating or engaging in social activity?"

☐	Not during the past month	ELIGIBLE
☐	Less than once per week	ELIGIBLE
☐	Once or twice per week	NOT ELIGIBLE
☐	Three or more times per week	NOT ELIGIBLE

k. Provide additional information:

_____
_____
_____
_____
_____
_____

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Month 1 Visit** (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Has the participant experienced any new adverse events, have any existing events changed in severity or frequency, or has any adverse event ended?

   ☐1 Yes ☐0 No

   (If **YES**, update the Adverse Event Log)

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose?

   ☐1 Yes ☐0 No

   (If **YES**, update the Concomitant Medication Log)

3. Has blood been drawn?

   ☐1 Yes ☐0 No

   If **No**, explain:_____

   If **YES**, what time was the blood drawn? __ __ : __ __ ☐1 AM ☐2 PM

   If **Yes**, was participant fasting? ☐1 Yes ☐0 No

4. Has a urine specimen been collected?

   ☐1 Yes ☐0 No

   If **No**, explain:_____

5. Has the participant used a PDE-5 inhibitor for erectile dysfunction since his last visit?

   ☐1 Yes ☐0 No

   If **YES**, indicate which PDE-5 Inhibitor was used:

   ☐ Viagra or Sildenafil

   ☐ Levitra or Vardenafil

   ☐ Cialis or Tadalafil

   (If any of the above medications were used, also update the Concomitant Medication Log)

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Month 2 Visit** (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Has the participant experienced any new adverse events, have any existing events changed in severity or frequency, or has any adverse event ended? ☐$_1$ Yes ☐$_0$ No

   (If **YES**, update the Adverse Event Log)

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose? ☐$_1$ Yes ☐$_0$ No

   (If **YES**, update the Concomitant Medication Log)

3. Has blood been drawn? ☐$_1$ Yes ☐$_0$ No

   If **No**, explain:_____

   If **YES**, what time was the blood drawn? __ __ : __ __ ☐$_1$ AM ☐$_2$ PM

   If **Yes**, was participant fasting? ☐$_1$ Yes ☐$_0$ No

4. Has a urine specimen been collected? ☐$_1$ Yes ☐$_0$ No

   If **No**, explain:_____

5. Has the participant used a PDE-5 inhibitor for erectile dysfunction since his last visit? ☐$_1$ Yes ☐$_0$ No

   If **YES**, indicate which PDE-5 Inhibitor was used:

   ☐ Viagra or Sildenafil

   ☐ Levitra or Vardenafil

   ☐ Cialis or Tadalafil

   (If any of the above medications were used, also update the Concomitant Medication Log)

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Month 3 Visit** (Research Coordinator Completed)	Participant ID: Participant Initials: Site: Date:

1. Has the participant experienced any new adverse events, have any existing events changed in severity or frequency, or has any adverse event ended? ☐1 Yes ☐0 No

   (If **YES**, update the Adverse Event Log)

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose? ☐1 Yes ☐0 No

   (If **YES**, update the Concomitant Medication Log)

3. Has blood been drawn? ☐1 Yes ☐0 No

   If **NO**, explain:_____

   If **YES**, what time was the blood drawn? __ __ : __ __ ☐1 AM ☐2 PM

   If **YES**, was participant fasting? ☐1 Yes ☐0 No

4. Has a urine specimen been collected? ☐1 Yes ☐0 No

   If **NO**,explain:_____

5. Was Digital Rectal Exam performed? ☐1 Yes ☐0 No

   If **NO**, explain:_____

   If **YES**, results: ☐1 Normal ☐2 Abnormal

   If **ABNORMAL**, does the participant have a prostate nodule? ☐1 Yes ☐0 No

   If YES, participant must be referred for evaluation.

5a. What is the size of the prostate?

   ☐1 Normal

   ☐2 Mildly enlarged

   ☐3 Moderately enlarged

   ☐4 Very enlarged

6. Has the participant used a PDE-5 inhibitor for erectile dysfunction since his last visit? ☐1 Yes ☐0 No

   If **YES**, indicate which PDE-5 Inhibitor was used:

   ☐1 Viagra or Sildenafil

   ☐2 Levitra or Vardenafil

   ☐3 Cialis or Tadalafil

   (If any of the above medications were used, also update the Concomitant Medication Log)

7. Were IVR forms and instructions provided? ☐1 Yes ☐0 No

1. Has the participant experienced any new adverse events, have any existing events changed in severity or frequency, or has any adverse event ended? ☐1 Yes ☐0 No

   (If **YES**, update the Adverse Event Log)

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose? ☐1 Yes ☐0 No

   (If **YES**, update the Concomitant Medication Log)

Administrative Section: Do not data enter

Remind Participant to take the Gel

Please remind the participant to take gel every day at the dose listed on the DOSE log, then answer the question below. Note this question does not need to be entered into the TTrial Data Management System:

Did you remind the participant to apply gel every day at his current dose? ☐1 Yes ☐0 No

Please review the Gel Use Instructions Sheet with the participant over the phone.

While using the Gel Use Review Sheet, please highlight the following areas:

You are currently at X dose and I want to remind you to use the gel and apply it to your body every day. Remember to apply the gel to your shoulders, upper arms or stomach in the morning. Do not apply the gel to your chest or to broken skin. When you are applying the gel, fully depress the pump all the way down, X times.

Do you have any questions about gel application? Have you been having any problems applying the gel to your body?

For men who recently had a dose reduction, per the DOSE log:

I know you recently had a dose reduction, down to X depressions, but I want to remind you how important it is to continue to use the gel at this exact dose every day. This dose is specific to you and has been tailored to your lab values so please continue to use the gel at this dose, daily, unless you hear differently.

1. Has the participant experienced any new adverse events, have any existing events changed in severity or frequency, or has any adverse event ended?

☐1 Yes ☐0 No

(If **YES**, update the Adverse Event Log)

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose?

☐1 Yes ☐0 No

(If **YES**, update the Concomitant Medication Log)

Administrative Section: Do not data enter

Remind Participant to take the Gel

Please remind the participant to take gel every day at the dose listed on the DOSE log, then answer the question below. Note this question does not need to be entered into the TTrial Data Management System:

Did you remind the participant to apply gel every day at his current dose? ☐1 Yes ☐0 No

Please review the Gel Use Instructions Sheet with the participant over the phone.

While using the Gel Use Review Sheet, please highlight the following areas:

You are currently at X dose and I want to remind you to use the gel and apply it to your body every day. Remember to apply the gel to your shoulders, upper arms or stomach in the morning. Do not apply the gel to your chest or to broken skin. When you are applying the gel, fully depress the pump all the way down, X times.

Do you have any questions about gel application? Have you been having any problems applying the gel to your body?

For men who recently had a dose reduction, per the DOSE log:

I know you recently had a dose reduction, down to X depressions, but I want to remind you how important it is to continue to use the gel at this exact dose every day. This dose is specific to you and has been tailored to your lab values so please continue to use the gel at this dose, daily, unless you hear differently.

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Month 6 Visit** (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Has the participant experienced any new adverse events, have any existing events changed in severity or frequency, or has any adverse event ended?

   ☐1 Yes ☐0 No

   (If **YES**, update the Adverse Event Log)

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose?

   ☐1 Yes ☐0 No

   (If **YES**, update the Concomitant Medication Log)

3. Has blood been drawn?

   ☐1 Yes ☐0 No

   If **NO**, explain: _____

   If **YES**, what time was the blood drawn? __ __ : __ __ ☐1 AM ☐2 PM

   If **YES**, was participant fasting? ☐1 Yes ☐0 No

4. Has a urine sample been collected?

   ☐1 Yes ☐0 No

   If **NO**, explain: _____

5. Has the participant used a PDE-5 inhibitor for erectile dysfunction since his last visit?

   ☐1 Yes ☐0 No

   If **YES**, indicate which PDE-5 Inhibitor was used:

   ☐ Viagra or Sildenafil

   ☐ Levitra or Vardenafil

   ☐ Cialis or Tadalafil

   (If any of the above medications were used, also update the Concomitant Medication Log)

6. Were IVR forms and instructions provided?

   ☐1 Yes ☐0 No

1. Has the participant experienced any new adverse events, have any existing events changed in severity or frequency, or has any adverse event ended?

☐1 Yes ☐0 No

(If **YES**, update the Adverse Event Log)

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose?

☐1 Yes ☐0 No

(If **YES**, update the Concomitant Medication Log)

Administrative Section: Do not data enter

Remind Participant to take the Gel

Please remind the participant to take gel every day at the dose listed on the DOSE log, then answer the question below. Note this question does not need to be entered into the TTrial Data Management System:

Did you remind the participant to apply gel every day at his current dose? ☐1 Yes ☐0 No

Please review the Gel Use Instructions Sheet with the participant over the phone.

While using the Gel Use Review Sheet, please highlight the following areas:

You are currently at X dose and I want to remind you to use the gel and apply it to your body every day. Remember to apply the gel to your shoulders, upper arms or stomach in the morning. Do not apply the gel to your chest or to broken skin. When you are applying the gel, fully depress the pump all the way down, X times.

Do you have any questions about gel application? Have you been having any problems applying the gel to your body?

For men who recently had a dose reduction, per the DOSE log:

I know you recently had a dose reduction, down to X depressions, but I want to remind you how important it is to continue to use the gel at this exact dose every day. This dose is specific to you and has been tailored to your lab values so please continue to use the gel at this dose, daily, unless you hear differently.

1. Has the participant experienced any new adverse events, have any existing events changed in severity or frequency, or has any adverse event ended?

☐1 Yes ☐0 No

(If **YES**, update the Adverse Event Log)

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose?

☐1 Yes ☐0 No

(If **YES**, update the Concomitant Medication Log)

Administrative Section: Do not data enter

Remind Participant to take the Gel

Please remind the participant to take gel every day at the dose listed on the DOSE log, then answer the question below. Note this question does not need to be entered into the TTrial Data Management System:

Did you remind the participant to apply gel every day at his current dose? ☐1 Yes ☐0 No

Please review the Gel Use Instructions Sheet with the participant over the phone.

While using the Gel Use Review Sheet, please highlight the following areas:

You are currently at X dose and I want to remind you to use the gel and apply it to your body every day. Remember to apply the gel to your shoulders, upper arms or stomach in the morning. Do not apply the gel to your chest or to broken skin. When you are applying the gel, fully depress the pump all the way down, X times.

Do you have any questions about gel application? Have you been having any problems applying the gel to your body?

For men who recently had a dose reduction, per the DOSE log:

I know you recently had a dose reduction, down to X depressions, but I want to remind you how important it is to continue to use the gel at this exact dose every day. This dose is specific to you and has been tailored to your lab values so please continue to use the gel at this dose, daily, unless you hear differently.

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Month 9 Visit** (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Has the participant experienced any new adverse events, have any existing events changed in severity or frequency, or has any adverse event ended? ☐1 Yes ☐0 No

   (If **YES**, update the Adverse Event Log)

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose? ☐1 Yes ☐0 No

   (If **YES**, update the Concomitant Medication Log)

3. Has blood been drawn? ☐1 Yes ☐0 No

   If **No**, explain:_____

   If **YES**, what time was the blood drawn? __ __ : __ __ ☐1 AM ☐2 PM

   If **Yes**, was participant fasting? ☐1 Yes ☐0 No

4. Has a urine specimen been collected? ☐1 Yes ☐0 No

   If **No**, explain:_____

5. Has the participant used a PDE-5 inhibitor for erectile dysfunction since his last visit? ☐1 Yes ☐0 No

   If **YES**, indicate which PDE-5 Inhibitor was used:

   ☐ Viagra or Sildenafil

   ☐ Levitra or Vardenafil

   ☐ Cialis or Tadalafil

   (If any of the above medications were used, also update the Concomitant Medication Log)

6. Were IVR forms and instructions provided? ☐1 Yes ☐0 No

1. Has the participant experienced any new adverse events, have any existing events changed in severity or frequency, or has any adverse event ended?

☐1 Yes ☐0 No

(If **YES**, update the Adverse Event Log)

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose?

☐1 Yes ☐0 No

(If **YES**, update the Concomitant Medication Log)

Administrative Section: Do not data enter

Remind Participant to take the Gel

Please remind the participant to take gel every day at the dose listed on the DOSE log, then answer the question below. Note this question does not need to be entered into the TTrial Data Management System:

Did you remind the participant to apply gel every day at his current dose? ☐1 Yes ☐0 No

Please review the Gel Use Instructions Sheet with the participant over the phone.

While using the Gel Use Review Sheet, please highlight the following areas:

You are currently at X dose and I want to remind you to use the gel and apply it to your body every day. Remember to apply the gel to your shoulders, upper arms or stomach in the morning. Do not apply the gel to your chest or to broken skin. When you are applying the gel, fully depress the pump all the way down, X times.

Do you have any questions about gel application? Have you been having any problems applying the gel to your body?

For men who recently had a dose reduction, per the DOSE log:

I know you recently had a dose reduction, down to X depressions, but I want to remind you how important it is to continue to use the gel at this exact dose every day. This dose is specific to you and has been tailored to your lab values so please continue to use the gel at this dose, daily, unless you hear differently.

1. Has the participant experienced any new adverse events, have any existing events changed in severity or frequency, or has any adverse event ended?

☐$_1$ Yes ☐$_0$ No

(If **YES**, update the Adverse Event Log)

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose?

☐$_1$ Yes ☐$_0$ No

(If **YES**, update the Concomitant Medication Log)

Remind Participant to take the Gel

Please remind the participant to take gel every day at the dose listed on the DOSE log, then answer the question below. Note this question does not need to be entered into the TTrial Data Management System:

Did you remind the participant to apply gel every day at his current dose? ☐$_1$ Yes ☐$_0$ No

Please review the Gel Use Instructions Sheet with the participant over the phone.

While using the Gel Use Review Sheet, please highlight the following areas:

You are currently X dose and I want to remind you to use the gel and apply it to your body every day. Remember to apply the gel to your shoulders, upper arms or stomach in the morning. Do not apply the gel to your chest or to broken skin. When you are applying the gel, fully depress the pump all the way down, X times.

Do you have any questions about gel application? Have you been having any problems applying the gel to your body?

For men who recently had a dose reduction, per the DOSE log:

I know your currently had a dose reduction, down to X depressions, but I want to remind you how important it is to continue to use the gel at this exact dose every day. This dose is specific to you and has been tailored to your lab values so please continue to use the gel at this dose, daily, unless you hear differently.

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Month 12 Visit** (Research Coordinator Completed)	Participant ID: ☐☐☐☐☐ Participant Initials: ☐☐☐ Site: ☐☐☐ Date: ☐☐/☐☐/☐☐☐☐

1. Has the participant experienced any new adverse events, have any existing events changed in severity or frequency, or has any adverse event ended?
   ☐1 Yes ☐0 No
   (If **YES**, update the Adverse Event Log)

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose?
   ☐1 Yes ☐0 No
   (If **YES**, update the Concomitant Medication Log)

3. Has blood been drawn?
   ☐1 Yes ☐0 No

   If **NO**, explain:_____

   If **YES**, what time was the blood drawn? __ __ : __ __ ☐1 AM ☐2 PM

   If **YES**, was participant fasting? ☐1 Yes ☐0 No

4. Has a urine specimen been collected?
   ☐1 Yes ☐0 No

   If **NO**, explain:_____

5. Was Digital Rectal Exam performed?
   ☐1 Yes ☐0 No

   If **NO**, explain:_____

   If **YES**, results: ☐1 Normal ☐2 Abnormal

   If **ABNORMAL**, does the participant have a prostate nodule? ☐1 Yes ☐0 No

   If YES, participant must be referred for evaluation.

5a. What is the size of the prostate?
   ☐1 Normal
   ☐2 Mildly enlarged
   ☐3 Moderately enlarged
   ☐4 Very enlarged

6. Has the participant used a PDE-5 inhibitor for erectile dysfunction since his last visit? ☐$_1$ Yes ☐$_0$ No

   If **YES**, indicate which PDE-5 Inhibitor was used:

   ☐ Viagra or Sildenafil

   ☐ Levitra or Vardenafil

   ☐ Cialis or Tadalafil

   (If any of the above medications were used, also update the Concomitant Medication Log)

7. Were IVR forms and instructions provided? ☐$_1$ Yes ☐$_0$ No

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Month 18 Visit** (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Has the participant experienced any new adverse events, have any existing events changed in severity or frequency, or has any adverse event ended?

☐1 Yes ☐0 No

(If **YES**, update the Adverse Event Log)

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose?

☐1 Yes ☐0 No

(If **YES**, update the Concomitant Medication Log)

3. Has blood been drawn?

☐1 Yes ☐0 No

If **No**, explain: _____

If **YES**, what time was the blood drawn? __ __ : __ __ ☐1 AM ☐2 PM

If **Yes**, was participant fasting? ☐1 Yes ☐0 No

4. Has the participant used a PDE-5 inhibitor for erectile dysfunction since his last visit?

☐1 Yes ☐0 No

If **YES**, indicate which PDE-5 Inhibitor was used:

☐ Viagra or Sildenafil

☐ Levitra or Vardenafil

☐ Cialis or Tadalafil

(If any of the above medications were used, also update the Concomitant Medication Log)

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Month 24 Visit** (Research Coordinator Completed)	Participant ID: Participant Initials: Site: Date:

1. Has the participant experienced any new adverse events, have any existing events changed in severity or frequency, or has any adverse event ended?

☐$_1$ Yes ☐$_0$ No

(If **YES**, update the Adverse Event Log)

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose?

☐$_1$ Yes ☐$_0$ No

(If **YES**, update the Concomitant Medication Log)

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

1. Has Trial Informed Consent been signed? ☐1 Yes ☐0 No

   If **YES,** Date of Consent: __ __/__ __/__ __ __ __
   MM DD YYYY

2. Has the participant started or stopped any medications (including vitamins, supplements, and minerals), or have any medications changed in frequency or dose? ☐1 Yes ☐0 No

   (If **YES**, update the Concomitant Medication Log)

3. Has blood been drawn? ☐1 Yes ☐0 No

   If **NO**, explain:_____

   If **YES**, what time was the blood drawn? __ __ : __ __ ☐1 AM ☐2 PM

   If **YES**, was participant fasting? ☐1 Yes ☐0 No

4. Has a urine specimen been collected? ☐1 Yes ☐0 No

   If **NO,** explain**:**_____

5. Is the participant currently taking an antidepressant? ☐1 Yes ☐0 No

   (If **YES**, update the Concomitant Medication Log)

6. Has the participant used a PDE-5 inhibitor for erectile dysfunction since his last visit? ☐1 Yes ☐0 No

   If **YES**, indicate which PDE-5 Inhibitor was used:

   ☐1 Viagra or Sildenafil

   ☐2 Levitra or Vardenafil

   ☐3 Cialis or Tadalafil

   (If any of the above medications were used, also update the Concomitant Medication Log)

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Screening Visit 1** (Research Coordinator Completed)	Participant ID: ☐☐☐☐☐☐☐☐ Participant Initials: ☐☐☐ Site: ☐☐ Date: ☐☐☐☐☐☐☐☐

1. Has the participant signed the Screening Informed Consent? ☐1 Yes ☐0 No

   If **YES**, Date of Consent: __ __/__ __/__ __ __ __ (MM / DD / YYYY)

2. Did the participant bring their medications (including vitamins, supplements, and minerals), or a listing of their medications to be recorded for study purposes? ☐1 Yes ☐0 No

   (If **YES**, update the Concomitant Medication Log)

3. Has blood been drawn? ☐1 Yes ☐0 No

   If **NO**, explain:_____

   If **YES**, what time was the blood drawn? __ __ : __ __ ☐1 AM ☐2 PM

   If **YES**, was participant fasting? ☐1 Yes ☐0 No

4. Does participant have a working touch-tone telephone for IVR use? ☐1 Yes ☐0 No

   If **NO**, was a touch-tone telephone provided? ☐1 Yes ☐0 No

---

Note: For Questions 5 – 10, please transcribe the information from the Pre-Screen (PSCR) Form, respond to any additional questions, and enter the data into the Data Management System (DMS).

5. What Screening ID Number was used for the participant's Pre-Screen Visit? __ __ __ __ __ __

6. Does the participant have difficulty walking a quarter of a mile? ☐1 Yes ☐0 No

   If NO, not eligible for Physical Function Trial.

   If **YES**, did the participant report needing help from another person to walk around his house or apartment? ☐1 Yes ☐0 No

   If YES, not eligible for Physical Function Trial.

7. Is the participant concerned that his energy is low? ☐1 Yes ☐0 No

   If NO, not eligible for Vitality Trial.

8. Has the participant's desire for sex decreased? ☐1 Yes ☐0 No

   If **YES**, did the participant indicate if he had a sexual partner who was willing to have sexual intercourse two or more times a month? ☐1 Yes ☐0 No

If NO, not eligible for Sexual Function Trial.

9. Did the participant report being diagnosed with Sleep Apnea? ☐1 Yes ☐0 No

10. Did the participant report being treated for cancer, or has the participant been told by a doctor they had cancer or a malignant tumor (within the past 3 years)? ☐1 Yes ☐0 No

    If **YES**, which of the following did they report they had?

☐ Leukemia / Lymphoma ☐ Pancreas ☐ Head or Neck ☐ Thyroid

☐ Lung ☐ Colon / Rectal ☐ Breast

☐ ***Bladder*** ***Surgery for Bladder Cancer?*** ☐1 Yes ☐0 No ***Was this reviewed by medical team?*** ☐1 Yes – determined eligible to continue ☐0 No – determined ineligible

☐ ***Nonmelanoma Skin*** ***Was this reviewed by medical team?*** ☐1 Yes – determined eligible to continue ☐0 No – determined ineligible

☐ ***Other Cancers***: _____ ***Was this reviewed by medical team?*** ☐1 Yes – determined eligible to continue ☐0 No – determined ineligible

_____

Is the participant currently receiving radiation treatment and or chemotherapy for their cancer? ☐1 Yes ☐0 No

If **YES**, participant is ineligible. If **NO**, was this reviewed by medical team? ☐1 Yes – determined eligible to continue ☐0 No – determined ineligible

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11. Is participant eligible for screening visit 2? ☐1 Yes ☐0 No

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Demographic Information** Screening Visit 1 (Research Coordinator Completed)	Participant ID: Participant Initials: Site: Date:

1. Date of Birth: __ __/__ __/__ __ __ __ (mm/dd/yyyy)

2. Ethnicity:
   - ☐1 Hispanic/Latino
   - ☐2 Not Hispanic/Latino

3. Race: (check all that apply)
   - ☐ North American Indian/Alaskan Native
   - ☐ Asian
   - ☐ Black/African American
   - ☐ Native Hawaiian/Other Pacific Islander
   - ☐ White/Caucasian
   - ☐ Other _____

4. Marital status:
   - ☐1 Never married
   - ☐2 Currently married
   - ☐3 Living with a partner
   - ☐4 Divorced
   - ☐5 Separated
   - ☐6 Widowed

5. Highest level of education completed:
   - ☐1 8th grade or less
   - ☐2 9th to 12th grade, no high school diploma
   - ☐3 High school graduate or equivalent (e.g. GED)
   - ☐4 Technical or vocational school degree
   - ☐5 Some college education, but not completed degree
   - ☐6 College graduate
   - ☐7 Professional or graduate degree (e.g. Master's, PhD, JD, MD)

6. Is participant visually impaired? ☐1 Yes ☐0 No

   If YES, does participant wear eye glasses or contacts? ☐1 Yes ☐0 No

7. Is participant hearing impaired? ☐1 Yes ☐0 No

   If YES, does participant use an assistive hearing device? ☐1 Yes ☐0 No

   If YES, on which ear is the device used?
   - ☐1 Right
   - ☐2 Left
   - ☐3 Both

8. Does the participant comprehend and respond in English? ☐1 Yes ☐0 No

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Medical History 1** Screen Visit 1 (Research Coordinator Completed)	Participant ID: Participant Initials: Site: Date:

1. Has a doctor ever told you that you had heart failure or congestive heart failure? ☐1 Yes ☐0 No
If YES, answer question 1a.

   1a. Does this condition prevent you from walking two or three blocks or up a flight of stairs? ***If YES, Ineligible***. ☐1 Yes ☐0 No

2. Has a doctor ever told you that you have chronic lung disease such as chronic bronchitis, COPD, asthma, or emphysema? **If YES, answer question 2a.** ☐1 Yes ☐0 No

   2a. Does this condition require you to wear oxygen or to regularly take steroid pills or injections? ***If YES, Ineligible***. ☐1 Yes ☐0 No

Script: This next question is about drinking alcoholic beverages. Alcoholic beverages include beer, wine and wine coolers and liquor like whisky or vodka, or cocktails. A drink is one 12 ounce can of beer, a five ounce glass of wine or a drink containing a "shot", a "jigger" or a "finger of liquor".

3. During the past 12 months, how many drinks did you have in a typical week? Number of Drinks _____

   If you are unsure, please make your best guess.

   If Number of drinks > 14 per week, then ineligible.

4. Have you used drugs other than those prescribed by a physician or purchased in a pharmacy or store? **If YES, answer question 4a. If NO, skip to question 5.** ☐1 Yes ☐0 No

   4a. What were they (check all that apply)?
   - ☐ Marijuana
   - ☐ Heroin or other opiods
   - ☐ Cocaine or other stimulants
   - ☐ Other, specify:_____

   If Any of the above were selected, answer question 4b.

   4b. How long ago were they used?
   - ☐1 Within the past year ***If within the past year, then ineligible.***
   - ☐2 Longer than 1 year

5. Since the age of 60, have you seen a doctor for emotional, nervous, or psychiatric problems? **If YES, answer questions 5a, 5b and 5c.** ☐1 Yes ☐0 No

   5a. Were you seen for bipolar disease? ***If YES, ineligible.*** ☐1 Yes ☐0 No

   5b. Were you seen for schizophrenia? ***If YES, ineligible.*** ☐1 Yes ☐0 No

   5c. Were you seen for depression? ☐1 Yes ☐0 No
   If YES, answer questions 5d, and 5e (if applicable).

   5d. Was this depression diagnosed within the past 3 months? ☐1 Yes ☐0 No
   If YES, need review by medical team for eligibility.

   5e. Were you seen for some other problem: ☐1 Yes ☐0 No

   Specify _____

   If YES, need review by medical team for eligibility.

6. Are you currently being treated for a skin condition such as psoriasis or eczema? **If YES, describe on question 6a.** ☐1 Yes ☐0 No

6a. Describe skin condition at the application site: ☐1 Normal ☐2 Abnormal

If ABNORMAL, describe: _____

If ABNORMAL, need review by medical team.

Was this abnormality reviewed by medical team?
☐1 Yes – determined eligible to continue
☐0 No – determined ineligible to continue

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Prostate Cancer Risk Calculator** Screening Visit 1 (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

Research Coordinator completes questions 1-7

1. What is the participant's race?
   - ☐ 1 African American
   - ☐ 2 Caucasian
   - ☐ 3 Hispanic
   - ☐ 98 Other
2. What is the participant's age? __ __
3. Does the participant have a family history of Prostate Cancer?
   Choose "Yes" if a father, brother, or son had prostate cancer.
   ☐ 1 Yes ☐ 0 No
4. What are the participant's Digital Rectal Exam results?
   For the purposes of this form, <u>at this visit only</u>, the results of the DRE are assumed to be "Normal".
   ☐ 1 Normal ☐ 2 Abnormal
5. Has the participant had a prior prostate biopsy?
   - ☐ 1 Never had a biopsy
   - ☐ 2 Past negative biopsy
   - ☐ 3 Past positive biopsy
6. Is the participant currently taking Finasteride or Proscar?
   ☐ 1 Yes ☐ 0 No
7. Is the participant currently taking Dutasteride or Avodart?
   ☐ 1 Yes ☐ 0 No

Questions 8 and 9 are completed in data management system.

8. Participant status:
   - ☐ Eligible
   - ☐ Ineligible
   - ☐ Lab results pending after 2 weeks
9. Check box to confirm review of participant status. ☐ 1

Screening Visit 1 [SV1] FAQ

How will the site staff know if a participant is eligible since the staff is blinded?

There are 2 ways to know –

- You will see the actual value of the *ineligible* T results. If the T result is eligible, you will be blinded, which is shown as a * on the Quest report.
- If the DCC asks for the RISK form that means that the T level is eligible and will be used with the PSA to calculate prostate cancer risk.

In Jan. when the entire system is accessible, you will see this information in the data management system. It is described in the MOP in section 6a2e - Prostate Cancer Risk Calculation (RISK).

[SCVST 1 Q #4a] What should we do if a man says he does not have a touchtone phone or service for a landline in his home?

You can discuss other options with this man such as; using his cell phone, if he has one, or going over to a friend or family member's house. However, you should explain the IVR system in detail and also explain the time commitment related to the system. If the man does not think it is feasible for him to complete the questionnaires on his cell phone or at another person's home, then he would not be eligible for the trial. Since the IVR is required of all participants, it is important that you discuss the process with men who do not have service for a landline in their homes.

[SCVST1 Q #10] There will be participants with specific cancers reported at Prescreening that require evaluation at Screening Visit 1. How specifically should this be done? Which questions should be asked to clear someone for trial participation, especially for bladder cancer? In the case of non-melanoma cancer (such as basal cell and squamous) what criteria will make a man ineligible?

The purpose of evaluating men who report bladder cancer, nonmelanoma skin cancer or other cancers is to exclude participants with cancers that are likely to recur. This evaluation should seek to determine that a participant does not have active disease.

Note: If a participant reports that he has sarcoma, he must be excluded.

[SCVST1 Q #11] The Question asks, "is the participant eligible to proceed to screening visit 2," how will we know the answer to this question without receiving the testosterone lab work form Quest?

This question should be answered based upon the information you have gathered at screening visit 1.

[SCVST1 Q #'s 1 and 11] A man came in for screening visit 1 (SV1) and, after reading the consent form, decided not to participate in the trial, should his data be entered?

Yes, for this man enter questions 1 and 11 on the screening visit 1 case report form **(SCVST1).** This will indicate the man did not consent and was not eligible to proceed to the screening visit 2 (SV2) visit. Mark all of the other case reports forms (CRFs) from that visit as left intentionally blank so they do not generate queries or discrepancies.

[MHX1 Q #4] If a man reports that he is prescribed marijuana for medical purposes, would he be eligible for the study?

Marijuana is exclusionary if used recreationally but if it is prescribed for medical use, then it is not exclusionary. This man should not be excluded.

[RISK] If a man had a past positive PIN, but a negative prostate biopsy, how should this be recorded and is this man eligible to proceed?

A past positive PIN renders a man ineligible for the study, per the study inclusion criteria; participant has diagnosed prostate cancer or prostatic intraepithelial neoplasia (PIN). This is listed as an exclusion criterion in the protocol and on the ELIG CRF. If a man reveals he had a past positive PIN he should be excluded, and a RISK form should not be completed.

This would not be recorded on the RISK form as the RISK form only has 3 specific categories: never had a prostate biopsy, had a past positive prostate biopsy or had a past negative prostate biopsy.

[RISK Q #3] When completing the Prostate Cancer Risk Calculator at Screening Visit 1, if a participant reports that he is adopted and has no knowledge of his family history, should the response to the question about family history of prostate cancer be 'NO' since there is not a selection for 'DON'T KNOW?'

Reply 'NO' when the family history of prostate cancer is unknown.

[RISK Q #4] The Digital Rectal Exam (DRE) has not been performed yet, what should I put on the RISK CRF?

For the RISK CRF assume that the DRE is normal. Make sure to fill in the answer as normal and do not leave the question blank or the answer will not generate.

How do I know when to enter the RISK CRF?

When you receive T results from Quest, if they are within the eligible range, which will be blinded, and the creatnine and ALT levels meet the inclusion criteria for the study; enter the RISK form in the DMS. The form will turn RED when the data has been imported from Quest and the risk algorithm is run. When the form is RED go in to manage the query by checking question #9 and acknowledging that the participant is eligible or ineligible based upon prostate cancer risk.

The form will also turn RED if the lab results have been pending for 2 weeks or more. If you see this indicated on the form you should contact Quest. The risk algorithm can not run until the data is imported.

If RISK forms are entered on ineligible men they will turn red after 2 weeks because the lab results will not be imported. The DCC will handle these forms entered in error.

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Testosterone Evaluation** **T < 100 at SV1 or SV2** (Research Coordinator Completed)	Participant ID: __ __ __ __ __ __ Participant Initials: __ __ __ Site: __ __ Date: __ __/__ __/__ __ __ __

1. Participant has been informed that T level is < 100 ng/dL ☐ Yes ☐ No

2. The following lab tests were conducted:

   a. Serum LH _____ mIU/mL ☐ NA

   b. Total T4 _____ ug/dL ☐ NA

   c. Prolactin _____ ng/mL ☐ NA

   d. Cortisol _____ ug/dL ☐ NA

   e. Testosterone _____ ng/dL ☐ NA

   f. Other: _____ _____ ☐ NA

   g. Other: _____ _____ ☐ NA

3. Medical history has been evaluated for:

   a. Mumps orchitis ☐ Yes ☐ No

   b. Castration ☐ Yes ☐ No

   c. Klinefelter's syndrome ☐ Yes ☐ No

   d. Chemotherapy with elevated LH ☐ Yes ☐ No

4. Participant had an MRI scan of the head: ☐ Yes ☐ No

   a. If YES, provide additional information.

   _____

   _____

   _____

5. Participant has been medically evaluated by a physician and has been cleared to proceed in the TTRIAL screening process. ☐ Yes ☐ No

   a. If YES, participant has been informed that the standard medical treatment for a serum T level of < 100 is testosterone replacement, and that there is a 50% chance he would receive placebo (not testosterone) for one year if he participates in the TTRIAL? ☐ Yes ☐ No

1. **Sample Test A**

   Number of Errors _____

   Time (In seconds) __ __ __

   Was test discontinued? ☐$_1$ Yes ☐$_0$ No

2. **Test A**

   Number of Errors _____

   Time (In seconds) __ __ __

   Was test discontinued? ☐$_1$ Yes ☐$_0$ No

3. **Sample Test B**

   Number of Errors _____

   Time (In seconds) __ __ __

   Was test discontinued? ☐$_1$ Yes ☐$_0$ No

4. **Test B**

   Number of Errors _____

   Time (In seconds) __ __ __

   Was test discontinued? ☐$_1$ Yes ☐$_0$ No

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **UCLA Harbor** **Psychosexual Daily Questionnaire** Visit __ __ *(Participant Completed via IVR)*	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Please rate your overall sexual desire today by entering the appropriate number :

   0 1 2 3 4 5 6 7
   none very low very high

2. Please rate highest level of enjoyment or pleasure of any sexual activity that you experienced today.

   (a) without a partner (e.g. masturbation or sexual fantasies) (b) with a partner (e.g. kissing, intercourse) by entering the appropriate number .

2a. Without a partner 0 1 2 3 4 5 6 7
   none very high enjoyment/pleasure

2b. With a partner 0 1 2 3 4 5 6 7
   none very high enjoyment/pleasure

2c. Please indicate if partner is available ☐ Yes ☐ No

3. Please rate your mood by entering the number that corresponds to the following scale. For each item 0 indicates that the descriptor is not all true; 7 indicates that the descriptor is very true for you today.

   not at all true 0 1 2 3 4 5 6 7 very true

   a Angry ___ d Full of pep/energetic ___ g Friendly ___
   b Alert ___ e Sad or Blue ___ h Nervous ___
   c Irritable ___ f Tired ___ i Well/good ___

4. For all the items indicate Yes if you have experienced (or are experiencing) today, otherwise indicate No.

	Yes	No			Yes	No			Yes	No	
a	☐	☐	Sexual daydreams	e	☐	☐	Orgasm	i	☐	☐	Masturbation
b	☐	☐	Anticipation of sex	f	☐	☐	Flirting (by others toward you)	j	☐	☐	Night spontaneous erections
c	☐	☐	Sexual interactions with partner	g	☐	☐	Ejaculation	k	☐	☐	Day spontaneous erections
d	☐	☐	Flirting (by you)	h	☐	☐	Intercourse	l	☐	☐	Erection in response to sexual activity

<u>Answer the following two questions only if you experienced an erection as shown in question 4j - l</u>

5. If you experienced an erection today, indicate the % full erection that you experienced by entering the appropriate number below (make reasonable estimate)

   % = 0 10 20 30 40 50 60 70 80 90 100

6. If you experienced an erection today, indicate whether it was maintained for a satisfactory duration by entering the appropriate number:

   not satisfactory 0 1 2 3 4 5 6 7 very satisfactory

7. Day is relative of the reporting period/week (i.e. 1, 2, 3, 4, 5, 6 or 7): _____

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

COMPLETE PHOTOCOPIES OF THIS FORM WITH SIGNATURES MUST BE FAX TO THE DCC AT (215) 573-4790.

1. Date of Unblinding: __ __/__ __/__ __ __ __
   mm dd yyyy

2. Time of Unblinding: __ __:__ __ (Military time)

3. Why was the study medication unblinded?

   ☐1 Serious Adverse Event

   AE# as recorded on AE: __ __ __

   ☐98 Other

   Reason: _____

P.I. Signature: _____ Date: __ __/__ __/__ __ __ __
mm dd yyyy

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Unscheduled Blood Draw**	Participant ID:__ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. What is the primary reason for this Unscheduled Blood Draw?

   ☐$_1$ Redraw of specimen (clotted specimen)

   ☐$_2$ Redraw of specimen (partial sample collected at last visit)

   ☐$_3$ Redraw of specimen (other reason, describe: _____)

   ☐$_4$ Specimen not collected at last visit (indicate visit: __ __ __)

   ☐$_5$ Retest of previous sample – request from Data Coordinating Center

2. Name of lab test(s) redrawn. ***Check all that apply***

   ☐ Testosterone Total

   ☐ Chemistry Panel

   ☐ PSA

   ☐ CBC

   ☐ Hgb/Hct

   ☐ HgbA1c

   ☐ Urinalysis

   ☐ DHT

   ☐ TSH

   ☐ FSH/LH

3. What was the time of the Unscheduled Blood Draw? __ __ : __ __ ☐$_1$ AM ☐$_2$ PM

4. Was the participant fasting? ☐$_1$ Yes ☐$_0$ No

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **6 Minute Walk Test** Visit __ __ (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1. Did participant begin the 6 minute walk test? ☐1 Yes ☐0 No

2. Pre-test heart rate: __ __ __ bpm

3. Pre-test blood pressure: __ __ __ sys __ __ __ dia

4. Did participant use an assistive device? ☐1 Yes ☐0 No
   If Yes, answer question 4a.

   4a. What assistive device was used?

   ☐1 Walker
   ☐2 Cane
   ☐98 Other: _____

5. Did the participant complete the 6 minute walk test? ☐1 Yes ☐0 No

6. Post test heart rate? __ __ __ bpm

7. Total Time Elapsed: __ __ min __ __ sec

   7a. Total Laps Walked: __ __ laps completed

   7b. Total Additional Meters Walked: __ __ additional meters

   7c. Walk Speed: ***(Calculated by DMS)*** __ __ __ meters/per second

8. Did the participant report any of the following symptoms during or at the end of the 6 minute walk test:
   (Check all that apply)

   ☐ None
   ☐ Chest Pain
   ☐ Feeling Faint or Dizzy
   ☐ Leg Pain
   ☐ Shortness of breath
   ☐ Other symptoms reported: _____

9. Were any of the following symptoms observed during or at the end of the participant's 6 minute walk test: ***(Check all that apply)***

- ☐ None
- ☐ Shortness of breath
- ☐ Wheezing / Dyspnea
- ☐ Signs of discomfort
- ☐ Unsteadiness
- ☐ Sweating
- ☐ Other symptoms observed: _____

10. What was the participant's perceived exertion based on the Borg RPE scale? __ __

11. Examiner ID: __ __ __

THE T TRIAL THE TESTOSTERONE TRIAL	**TESTOSTERONE TRIAL** **Wechsler Memory Scale Delayed Recall** Visit __ __ (Research Coordinator Completed)	Participant ID:__ __ __ __ __ __ Participant Initials __ __ __ Site: __ __ Date:__ __ / __ __ / __ __ __ __

1.	Record clock time at start	__ __:__ __ HH MM	☐1 AM	☐2 PM
2.	Story A: Was a reminder cue given?	☐1 Yes	0☐ No	
3.	Story A: Total Delayed Recall Score (0 – 25)	_____		
4.	Story B: Was a reminder cue given?	☐1 Yes	☐0 No	
5.	Story B: Total Delayed Recall Score (0 – 25)	_____		
6.	Total Sum of Logical Memory Delayed Recall (0 – 50)	_____		

1. Story A: Total Immediate Recall Score (0 – 25) _____

2. Story B: Total Immediate Recall Score (0 – 25) _____

3. Total Sum of stories A & B (0 – 50) _____

4. Record clock time at completion __ __:__ __ (HH MM) ☐1 AM ☐2 PM