Participant ID pid | D000000

Acrostic acrostic | ZZZZZ

Examiner compby | Visit Code vc | YYY

Date of Visit vis_dat | (mm/dd/yyyy)

400 Meter Walk (Follow-up Visits)

CRF 1.1

Stopping Criteria for 400 Meter Walk: If the participant reports chest pain, tightness or pressure, significant shortness of breath or difficulty breathing, or feeling faint, lightheaded or dizzy, <u>stop the test</u>. Record the reason for stopping.

Observations of 400 Meter Walk

Accompany the subject to the starting line of the 400 meter walk with script and stop watch. Describe the 400 meter walk:

Script: "Now I would like to observe how you normally walk. You will be walking 10 complete laps around the course, which corresponds to about 1/4 mile. I would like you to walk at your usual pace and without overexerting yourself. During this test, I will ask you to rate how hard you feel you are working. When I ask you to rate how hard you are working during the walk, I want you to think about the total feeling of exertion in your overall body, including your breathing and muscles. At the end of lap 4, while you continue walking, I will ask you how hard you are working. After you have completed all 10 laps, I will tell you to stop, ask you to rate the difficulty of your breathing, and then measure your heart rate. If you develop chest pain or significant shortness of breath, or are too uncomfortable to continue, please stop walking and tell me. If you need to, you may stand in place and rest for a few moments, but you may not lean against the wall or any other surface."

Did subject bring a cane, walker or other walking aid to the clinic?

walkdevf_w400

-9
1 Yes (Go to Attempt Script)
0 No (Go to Demonstration Script)
-6 Permanently Missing

[▼]

Attempt Script: " I would like you to attempt this test without your cane (or walker)." ,*Only a single straight cane may be used for the test; a walker may not be used.*
If subject is hesitant or indicates that s/he cannot do the test: **"You don't need to complete the test but I would like you to try it, even if you only take a few steps. I will be right beside you."**

1. Would you be willing to try the test and see how you feel?

willing_w400

-9
1 Yes (Go to Demonstration Script)
0 No (Go to Q2)
-6 Permanently Missing

[▼]

2. Did participant bring a single straight cane to the clinic?

walkdev_w400

-9
1 Yes (Go to Q2a)
0 No (Go to Q13)
-6 Permanently Missing

[▼]

2a. Would you be willing to try the test if you could use your cane?

safewkdv_w400

-9
1 Yes (Go to Demonstration Script)
0 No (Go to Q3)
-6 Permanently Missing

[▼]

3. Remember, you don't need to complete the test, but I would like you to try it, even if you only take a few steps. I will be right beside you. Can you give it a try?

safewkdvb_w400

-9
1 Yes (Go to Demonstration Script)
0 No (Go to Q13)
-6 Permanently Missing

[▼]

Demonstration Script: "I will demonstrate 1 lap." *After completing demonstration, ask :* **"Do you have any questions?"**

[For subjects who did not bring a cane or other walking aid to the clinic]

Is subject hesitant or indicates that s/he cannot do the test?

hesitant_w400
-9
1 Yes (Go to Q4)
0 No (Proceed with test)
-6 Permanently Missing

4.You don't need to complete the test, but I would like you to try it, even if you only take a few steps. I will be right beside you. Can you give it a try?

safetry_w400
-9
1 Yes (Proceed with test)
0 No (Go to Q13)
-6 Permanently Missing

When subject indicates they feel ready to begin, the test may proceed:

Script: "I will walk [beside] behind you, When I say "GO", start *walking at a comfortable pace you can maintain*. Ready, Go."

Start the stop watch when the subject takes their first step. If needed, for safety purposes, examiner should follow subject at a reasonable distance during test. Examiner should be close enough to subject to be able to provide help should subject falter during test, but not so close as to dictate the pace of the test. The examiner should be behind and to the side of the subject, just outside their peripheral vision. For every lap, the examiner should offer standard encouragement, and call out the number of laps completed and number remaining.

Script: "You're doing a good job. You have completed __ laps and have __ to go."

If the participant feels they need to stop and rest, they may underline stand in one place and rest. Participant should not lean on wall, table or any surface other than their cane. If they do lean, they should be immediately instructed not to do so and the test can continue. If participant needs to lean on wall, table or other surface for a second time during the rest stop or needs to lean again on a subsequent rest stop, stop the test (go to #7).

After 30 seconds, ask them if they can continue walking. If they can, continue the walk and note the rest on the form. (go on to #6)

If the participant appears to be in obvious distress or pain, you may recommend that he/she stand in place and rest for a moment. If they need to rest longer, have them continue to stand. After another 30 seconds, ask them if they can continue walking. If they can, continue the walk and note the rest stop on the form. (go on to #6)

If they cannot continue after a 60 second rest or if they need to sit down, stop the test. (go on to #7)

There is no limit to the number of rest stops as long as they can complete the walk without sitting. (record all stops on #6)

If the participant requests their cane, allow them to complete the test with the cane, and indicate below that a cane was used.

When an accelerometer is used please provide the following:				
Start Time		**Stop Time**		**Accelerometer ID##**
accelsrthr_w400 accelsrtmn_w400		accelstphr_w400 accelstpmn_w400		Last 4 digits of the serial number accelid_w400
H H M M (record time in a 24-hr clock)		H H M M (record time in a 24-hr clock)		

5. Mark an X in the corresponding box when each lap is completed

Lap 1	Lap 2	Lap 3	Lap 4	Please tell me how hard you feel you are working right now. Is it "light",	a. howhard_w400 -9 1 Light 2 Somewhat hard 3 Hard 4 Very Hard -6 Permanently Missing
lap1_w400 value	lap2_w400 value	lap3_w400 value	lap4_w400 value		*(If the participant reports "hard" or "very hard", read script below.)*

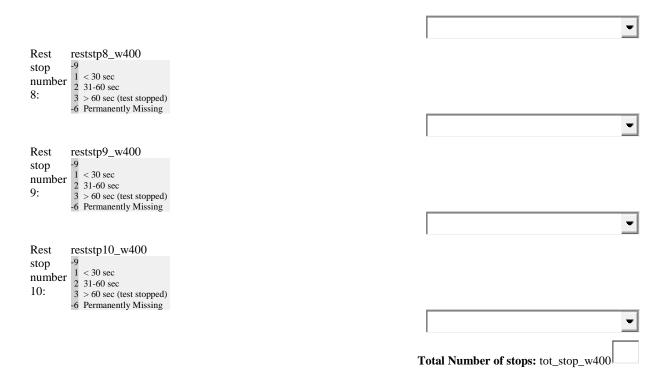| ="1" ☐	="1" ☐	="1" ☐	="1" ☐	"somewhat hard", "hard" or "very hard"?	

Script: I would like to remind you to walk at your usual pace without overexerting yourself. If you develop chest pain or significant shortness of breath, or are too uncomfortable to continue, please stop walking and tell me. If you need to, you may stand in place and rest for a few moments.

Lap 5	Lap 6	Lap 7	Lap 8	Lap 9	Lap 10
lap5_w400 value="1" ☐	lap6_w400 value="1" ☐	lap7_w400 value="1" ☐	lap8_w400 value="1" ☐	lap9_w400 value="1" ☐	lap10_w400 value="1" ☐

6. For each rest stop, Mark an X corresponding to the length of time of the rest (standing rests only):

Rest stop number 1:

reststp1_w400
-9
1 < 30 sec
2 31-60 sec
3 > 60 sec (test stopped)
-6 Permanently Missing

[dropdown]

Rest stop number 2:

reststp2_w400
-9
1 < 30 sec
2 31-60 sec
3 > 60 sec (test stopped)
-6 Permanently Missing

[dropdown]

Rest stop number 3:

reststp3_w400
-9
1 < 30 sec
2 31-60 sec
3 > 60 sec (test stopped)
-6 Permanently Missing

[dropdown]

Rest stop number 4:

reststp4_w400
-9
1 < 30 sec
2 31-60 sec
3 > 60 sec (test stopped)
-6 Permanently Missing

[dropdown]

Rest stop number 5:

reststp5_w400
-9
1 < 30 sec
2 31-60 sec
3 > 60 sec (test stopped)
-6 Permanently Missing

[dropdown]

Rest stop number 6:

reststp6_w400
-9
1 < 30 sec
2 31-60 sec
3 > 60 sec (test stopped)
-6 Permanently Missing

[dropdown]

Rest stop number 7:

reststp7_w400
-9
1 < 30 sec
2 31-60 sec
3 > 60 sec (test stopped)
-6 Permanently Missing

Rest stop number 8: reststp8_w400

-9
1 < 30 sec
2 31-60 sec
3 > 60 sec (test stopped)
-6 Permanently Missing

Rest stop number 9: reststp9_w400

-9
1 < 30 sec
2 31-60 sec
3 > 60 sec (test stopped)
-6 Permanently Missing

Rest stop number 10: reststp10_w400

-9
1 < 30 sec
2 31-60 sec
3 > 60 sec (test stopped)
-6 Permanently Missing

Total Number of stops: tot_stop_w400

7. If the test is terminated <u>prior to the subject completing 400 meters</u>, the point at which they stopped should be marked, and the subject accompanied to the nearest chair. After the subject is comfortably seated, their accomplished distance should be measured.

Complete laps will be counted as 40 meters each and the remaining incomplete lap should be measured with the Redi-Measure as described below . Record the total distance and time at termination of test.

If the participant stopped in the first half of the lap (after leaving the starting cone but before getting to the distant cone) then measure the distance from the starting cone to where they stopped. If the participant stopped in the second half of the lap (after leaving the distant cone but before getting back to the starting cone) then measure the distance from the distant cone to the stopping point and add 20 meters.

Did the participant complete the 400 meter walk?
(Record time that first foot crosses the finish line.)

walk_comp_w400

-9
1 Yes
0 No (specify)
-6 Permanently Missing

If No, Number of meters completed: m_cmp_w400 ☐ M

8. TIME to walk 400 meters or to stopping the test: walk_min_w400 ☐ Minutes walk_sec_w400 ☐ Seconds

a. Did the participant use a straight cane during the test? device_w400

-9
1 Yes
0 No
-6 Permanently Missing

BORG Index

"This is a scale that asks you to rate the difficulty of your breathing. It starts at number 0, where your breathing is causing you no difficulty at all, and progresses through to number 10, where your breathing difficulty is maximal. How much difficulty is your breathing causing you right now?" Ask the participant to specifically choose a number between 0 and 10, rather than the verbal descriptor.

Borg Grade borg_w400

-9 -
0 Nothing at all
.5 0.5 - Very, very slight (just noticeable)
1 Very slight
2 Slight
3 Moderate
4 Somewhat Severe

```
 5 Severe
 6 Severe
 7 Very Severe
 8 Very Severe
 9 Very, very severe (almost maximal)
10 Maximal
-8 Don't Know
-7 Refused
-6 Permanently Missing
```

[dropdown ▼]

9. Sitting Radial Pulse: beats per 30 seconds X2 = end_hr_w400 [____] bpm

10. If test stopped early, ask: **"Why did you feel you couldn't continue?"**

Shortness of stp_brth_w400 value="1"
breath ☐

Feeling Faint or stp_fnt_w400 value="1"
Dizzy ☐

Chest Pain stp_chst_w400 value="1"
☐

Fatigue stp_fat_w400 value="1"
☐

Leg Pain ☐
stp_leg_w400 value="1"

Other stp_oth_w400 value="1"
☐

(specify) stp_otspc_w400 [_____]

11. At end of walk ask, **"Is there anything bothering you?"**

end_both_w400
```
-9
 1 Yes (specify)
 0 No
-6 Permanently Missing
```
[dropdown ▼]

If Yes, please specify what: end_bospc_w400 [_____]

12. Observed Symptoms at end of walk: (check all that apply)

Shortness of obs_brth_w400 value="1"
breath ☐

Unsteadiness obs_unst_w400 value="1"
☐

Other obs_oth_w400 value="1"
☐

Wheezing / obs_whz_w400 value="1"
dyspnea ☐

Sweating obs_swt_w400 value="1"
☐

No obs_no_w400 value="1"
symptoms ☐
observed

Signs of obs_disc_w400 value="1"
discomfort ☐

Specify Other obs_otspc_w400 [_____]

13. Comments (If the participant does not attempt or complete the walk, please provide additional explanation about why the walk was not attempted or completed. Also, if the participant did not attempt the 400 m walk, IT IS VERY IMPORTANT to administer the Assistive Device Questionnaire and attempt the 4 m walk test of the SPPB.)

comments_w400

Have the participant complete (i.e. self administer) the Efficacy for Walking instrument immediately following the 400 M Walk at the 12- and 30-month follow up clinic visits. At the follow up assessment visits, the Efficacy for Walking instrument should be completed even if the participant did not finish the 400 M Walk.

Source Form Language: lang

-9	-
1	English
2	Spanish

L I F E

Participant ID

(affix ID label here)

Examiner

Acrostic ☐☐☐☐☐

Visit Code ☐☐☐

Date of Visit ☐☐ ☐☐ ☐☐☐☐
month   day   year

400 Meter Walk (Follow-up Visits)

Stopping Criteria for 400 Meter Walk: *If the participant reports chest pain, tightness or pressure, significant shortness of breath or difficulty breathing, or feeling faint, lightheaded or dizzy, stop the test. Record the reason for stopping.*

OBSERVATIONS OF 400 METER WALK

Accompany the subject to the starting line of the 400 meter walk with script and stop watch. Describe the 400 meter walk:

Script: "Now I would like to observe how you normally walk. You will be walking 10 complete laps around the course, which corresponds to about ¼ mile. I would like you to walk at your usual pace and without overexerting yourself. During this test, I will ask you to rate how hard you feel you are working. When I ask you to rate how hard you are working during the walk, I want you to think about the total feeling of exertion in your overall body, including your breathing and muscles. At the end of lap 4, while you continue walking, I will ask you how hard you are working. After you have completed all 10 laps, I will tell you to stop, ask you to rate the difficulty of your breathing, and then measure your heart rate. If you develop chest pain or significant shortness of breath, or are too uncomfortable to continue, please stop walking and tell me. If you need to, you may stand in place and rest for a few moments, but you may not lean against the wall or any other surface."

Participant ID

(affix ID label here)

| Did subject bring a cane, walker, or other walking aid to the clinic? | ☐ **Yes** ⟶ **Go to Attempt Script** |
| | ☐ **No** ⟶ **Go to Demonstration Script** |

Attempt Script: "I would like you to attempt this test without your cane (or walker)." *Only a single straight cane may be used for the test; a walker may not be used.*
If subject is hesitant or indicates that s/he cannot do the test: **"You don't need to complete the test, but I would like you to try it, even if you only take a few steps. I will be right beside you."**

1. Would you be willing to try the test and see how you feel?	☐ **Yes** ⟶ **Go to Demonstration Script**
	☐ **No** ⟶ **Go to Q2**
2. Did participant bring a single straight cane to the clinic?	☐ **Yes** ⟶ **Go to Q2a**
	☐ **No** ⟶ **Go to Q13**
2a. Would you be willing to try the test if you could use your cane?	☐ **Yes** ⟶ **Go to Demonstration Script**
	☐ **No** ⟶ **Go to Q3**
3. Remember, you don't need to complete the test, but I would like you to try it, even if you only take a few steps. I will be right beside you. Can you give it a try?	☐ **Yes** ⟶ **Go to Demonstration Script**
	☐ **No** ⟶ **Go to Q13**

Demonstration Script: "I will demonstrate 1 lap." *After completing demonstration, ask:* **"Do you have any questions?"**

[For subjects who did not bring a cane or other walking aid to the clinic]	
Is subject hesitant or indicates that s/he cannot do the test?	☐ **Yes** ⟶ **Go to Q4**
	☐ **No** ⟶ **Proceed with test**
4. You don't need to complete the test, but I would like you to try it, even if you only take a few steps. I will be right beside you. Can you give it a try?	☐ **Yes** ⟶ **Proceed with test**
	☐ **No** ⟶ **Go to Q13**

When subject indicates they feel ready to begin, the test may proceed:
Script: "I will walk [beside] behind you. When I say 'GO", start *walking at a comfortable pace you can maintain.* Ready, Go."

Start the stop watch when the subject takes their first step. For safety purposes, examiner should be close enough to subject to be able to provide help should subject falter during test, but not so close as to dictate the pace of the test. For every lap, the examiner should offer standard encouragement, and call out the number of laps completed and number remaining.
Script: **"You're doing a good job. You have completed __ laps and have __ to go."**

If the participant feels they need to stop and rest, they may stand in one place and rest. Participant should not lean on wall, table or any surface other than their cane. If they do lean, they should be immediately instructed not to do so and the test can continue. If participant needs to lean on wall, table or other surface for a second time during the rest stop or needs to lean again on a subsequent rest stop, stop the test (go to #7).

After 30 seconds, ask them if they can continue walking. If they can, continue the walk and note the rest on the form. (go on to #6)
If the participant appears to be in obvious distress or pain, you may recommend that he/she stand in place and rest for a moment. If they need to rest longer, have them continue to stand. After another 30 seconds, ask them if they can continue walking. If they can, continue the walk and note the rest stop on the form. (go on to #6)
If they cannot continue after a 60 second rest or if they need to sit down, stop the test.
(go on to #7)
There is no limit to the number of rest stops as long as they can complete the walk without sitting. (record all stops on #6)

If the participant requests their cane, allow them to complete the test with the cane, and indicate below that a cane was used.

When an accelerometer is used please provide the following:

Start Time			Stop Time			Acclerometer ID#
☐ ☐ H H	☐ ☐ M M	*(record time in a 24-hr clock)*	☐ ☐ H H	☐ ☐ M M	*(record time in a 24-hr clock)*	Last 4 digits of the serial number ☐ ☐ ☐ ☐

5. Mark an X in the corresponding box when each lap is completed.

Lap 1	Lap 2	Lap 3	Lap 4
☐	☐	☐	☐

Please tell me how hard you feel you are working right now. Is it "light", "somewhat hard", "hard" or "very hard"? →

a. ☐
1. Light
2. Somewhat hard
3. Hard
4. Very Hard

(If the participant reports "hard" or "very hard", read script below)

Lap 5	Lap 6	Lap 7	Lap 8	Lap 9	Lap 10
☐	☐	☐	☐	☐	☐

Script: I would like to remind you to walk at your usual pace without overexerting yourself. If you develop chest pain or significant shortness of breath, or are too uncomfortable to continue, please stop walking and tell me. If you need to, you may stand in place and rest for a few moments.

6. For each rest stop, Mark an X corresponding to the length of time of the rest(standing rests only):

	< 30 sec.	31-60 sec.	> 60 seconds (test stopped)
Rest stop number 1:	☐	☐	☐
Rest stop number 2:	☐	☐	☐
Rest stop number 3:	☐	☐	☐
Rest stop number 4:	☐	☐	☐
Rest stop number 5:	☐	☐	☐
Rest stop number 6:	☐	☐	☐
Rest stop number 7:	☐	☐	☐
Rest stop number 8:	☐	☐	☐
Rest stop number 9:	☐	☐	☐
Rest stop number 10:	☐	☐	☐

Total number of stops: ☐ ☐

Participant ID

(affix ID label here)

LIFE

Acrostic

Visit
Code

7. *If the test is terminated <u>prior to the subject completing 400 meters,</u> the point at which they stopped should be marked, and the subject accompanied to the nearest chair. After the subject is comfortably seated, their accomplished distance should be measured.*

   Complete laps will be counted as 40 meters and the remaining incomplete lap should be measured with the Redi-Measure as described below. Record the total distance and time at termination of test.
   If the participant stopped in the first half of the lap (after leaving the starting cone but before getting to the distant cone) then measure the distance from the starting cone to where they stopped. If the participant stopped in the second half of the lap (after leaving the distant cone but before getting back to the starting cone) then measure the distance from the distant cone to the stopping point and add 20 meters.

Number of
meters
completed:

M

Did the participant complete the 400 meter walk?
(Record time that first foot crosses the finish line.)

Yes ☐ **No** ☐ →

8. TIME to walk 400 meters or to stopping the test: ☐☐ Minutes ☐☐ Seconds

8a. Did the participant use a straight cane during the test?   **Yes** ☐ **No** ☐

BORG Index

"This is a scale that asks you to rate the difficulty of your breathing. It starts at number 0, where your breathing is causing you no difficulty at all, and progresses through to number 10, where your breathing difficulty is maximal. How much difficulty is your breathing causing you <u>right now</u>?"

Ask the participant to specifically choose a number between 0 and 10, rather than the verbal descriptor.

Borg Grade [   ]   ☐ Don't Know   ☐ Refused

Borg Grade	Dyspnea descriptor
0	Nothing at all
0.5	Very, very slight (just noticeable)
1	Very slight
2	Slight
3	Moderate
4	Somewhat severe
5	Severe
6	
7	Very severe
8	
9	Very, very severe (almost maximal)
10	Maximal

9. Sitting Radial Pulse*:* beats per 30 seconds X2 = ☐☐☐ bpm

10. If test stopped early, ask: **"Why did you feel you couldn't continue?"**

Shortness of Breath	☐	Feeling Faint or Dizzy	☐
Chest Pain	☐	Fatigue	☐
Leg Pain	☐	Other: (Specify) _____	☐

11. At end of walk ask, **"Is there anything bothering you?"**   Yes ☐   No ☐

If yes, please specify what: _____

12. Observed Symptoms at end of walk: (X all that apply)

Shortness of breath	☐	Unsteadiness	☐	Other: _____	☐
Wheezing / dyspnea	☐	Sweating	☐	No symptoms observed	☐
Signs of discomfort	☐				

13. Comments (If the participant does not attempt or complete the walk, please provide a detailed explanation about why the walk was not attempted or completed. Also, if the participant did not attempt the 400 m walk, IT IS VERY IMPORTANT to administer the Assistive Device Questionnaire and attempt the 4 m walk test of the SPPB.)

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____