#### Dataset name: w400\_v4.2

Participant ID pid D00000 Acrostic acrostic ZZZZ Examiner compby Visit Code vc YYY Date of Visit vis\_dat (mm/dd/yyyy)

# 400 Meter walk (Baseline Visit)

CRF 4.2

<u>Stopping Criteria for 400 Meter Walk:</u> 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."

If subject uses a cane or other assistive device: "I would like you to attempt this test without your cane (or other assistive device)." <u>Only a single straight cane may be used to complete the test; a walker or any other assistive device may not be used.</u>

<b>1.</b> Do you feel it would be safe to try to walk up and down this hallway 10 times?	safe_w400 -9 1 Yes (demonstrate) 0 No (Go to 3a) -8 Don't Know (Go to 2) -6 Permanently Missing
2. Would you be willing to try it and see how you feel?	willing_w400 -9 1 Yes (demonstrate) 0 No (Go to 3a) -6 Permanently Missing
<b>3.a</b> Did participant bring a single straight cane to the clinic?	walkdev_w400 -9 1 Yes (Go to Q.4) 0 No (Go to Q.3b) -6 Permanently Missing
<b>3.b</b> Did participant bring a walker or other assistive device to the clinic?	walkdevb_w400 -9 1 Yes (Go to Q.13) 0 No (Go to Q.13) -6 Permanently Missing
<b>4.</b> Do you feel it would be safe if you could use your cane?	safewkdv_w400 -9 1 Yes (demonstrate) 0 No (Go to Q.13)

Script: " I will demonstrate 1 lap." After completing demonstration, ask : "Do you have any questions?" When subject indicates they feel ready to begin, the test may proceed:

Script: "I will walk behind you, When I say "GO", start <u>walking at a comfortable pace you can maintain</u>. 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 <u>stand in one place and rest</u>. 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).

<u>After 30 seconds, ask them if they can continue walking. If they can,</u> 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. <u>After another 30 seconds, ask them if they can continue walking</u>. <u>If they can</u>, 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_v	w400accelsrtmn_ M M	w400 (record time in a 24-hr clock)	accelstphi	w400accelstpmr	n_w400 (record time in a 24-hr clock)	Last 4 digits of the serial number accelid_w400

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

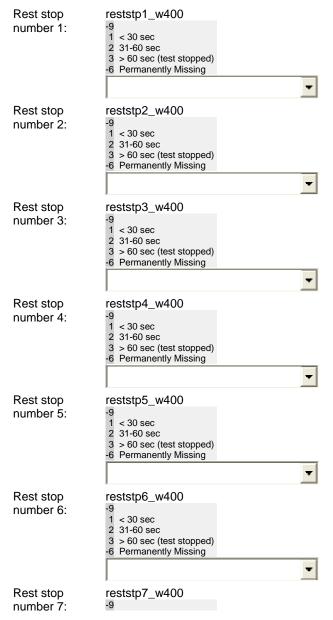
Lap 1	Lap 2	Lap 3	Lap 4	Please	a. howhard_w400
				tell me how hard you feel	-9 1 Light 2 Somewhat hard 3 Hard
				you are working right now. Is it	4 Very Hard -6 Permanently Missing

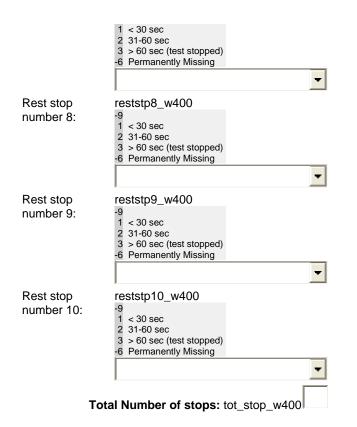
lap1_w400 value	lap2_w400 value	lap3_w400 value	lap4_w400 value	"light",	(If the participant reports
				"somewh	"hard" or "very hard",
="1"	="1"	="1"	="1"	at hard",	read script below.)
				"hard" or	. ,
				"very	
				hard"?	

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	lap6_w400 value	lap7_w400 value	lap8_w400 value	lap9_w400 value	lap10_w400 value
="1"	="1"	="1"	="1"	="1"	="1"

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





7. If the test is terminated prior to the subject completing 400 meters, 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, Nur	mber of meters completed: m_cmp_w400
8. TIME to walk 400 meters or to stopping the test: walk_min_w40 (Interviewer Note: Exclude if > 15 minutes and 0 seconds)	
<ul> <li>a. Did the participant use a straight cane during the test? device</li> <li>9 <ol> <li>Yes</li> <li>No</li> <li>-6 Permanently Missing</li> </ol> </li> </ul>	3_w400
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 pro How much difficulty is your breathing between 0 and 10, rather than the ver	causing you right now?'			
Borg Grade borg_w400				
<ul> <li>-9</li> <li>-1</li> <li>O Nothing at all</li> <li>5</li> <li>0.5 - Very, very slight (just noticeable)</li> <li>1 Very slight</li> <li>2 Slight</li> <li>3 Moderate</li> <li>4 Somewhat Severe</li> <li>5 Severe</li> <li>6 Severe</li> <li>7 Very Severe</li> <li>8 Very Severe</li> <li>9 Very, very severe (almost maximal)</li> <li>10 Maximal</li> <li>-8 Don't Know</li> <li>-7 Refused</li> <li>-6 Permanently Missing</li> </ul>	•			
9. Sitting Radial Pulse: beats per 30 s	seconds X2 = end_hr_w	/400 bpm		
10. If test stopped early, ask: "Why d				
Shortness stp_b of breath	rth_w400 value="1"	Feeling stp_fnt Faint or Dizzy	_w400 value="1"	
Chest Pain stp_c	hst_w400 value="1"	Fatigue stp_fat	_w400 value="1"	
Leg Pain stp_le	eg_w400 value="1"	Other stp_oth	_w400 value="1"	
		(specif	y) stp_otspc_w400	
11. At end of walk ask, "Is there anyt	hing bothering you?"		_	end_both_w400
			(	9 1 Yes (specify) 9 No 9 Permanently Missing
				<b>_</b>
If Yes, please spe	cify what: end_bospc_w	v400		
12. Observed Symptoms at end of wa	alk: (check all that apply	')		
Shortness obs_brth_w400 value="1 of breath	Unsteadines obs_uns s <b>"</b>	t_w400 value="1	Other obs_ot "	h_w400 value="1
Wheezing obs_whz_w400 value="1 / dyspnea <sub>"</sub>	Sweating obs_swt	_w400 value="1"	symptom s	o_w400 value="1"
Signs of obs_disc_w400 value="1 discomfor t "	Specify Other obs	_otspc_w400	observed	





Have the participant complete (i.e. self administer) the Efficacy for Walking instrument immediately following the 400 M Walk at SV1 (or at SV2 if not completed at SV1). At SV1/SV2, the Efficacy for Walking instrument need not be completed if the participant did not finish the 400 M Walk within 15 minutes.

Source Form Language: lang -9 -1 English 2 Spanish -

	LIFE	ŀ	Acrostic			
Participant ID (affix ID label here)		te of Visit		Visit Code	year	

### 400 Meter Walk (Baseline Visit)

<u>Stopping Criteria for 400 Meter Walk:</u> 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 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."

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Visit Code	

(affix ID label here)

Participant ID

If subject uses a cane or other assistive device: "I would like you cane (or other assistive device)." <u>Only a single straight cane may walker or any other assistive device may not be used.</u>					
<ol> <li>Do you feel it would be safe to try to walk up and down this hallway 10 times?</li> </ol>	Yes → Read script below No → Go to Q3a Don't Know→ Go to Q2				
2. Would you be willing to try it and see how you feel?	Yes     →     Read script below       No     →     Go to Q3a				
<i>3a. Did participant bring a single straight cane to the clinic?</i>	Yes → Go to Q4 No → Go to Q3b				
<i>3b. Did participant bring a walker or other assistive device to the clinic?</i>	Yes → Go to Q13 No → Go to Q13				
4. Do you feel it would be safe if you could use your cane?	Yes →       Read script below         No →       Go to Q13				
Script: "I will demonstrate 1 Iap." After completing demonstration, ask: "Do you have any questions?" When subject indicates they feel ready to begin, the test may proceed: Script: "I will walk behind you, When I say 'GO", start <u>walking at a comfortable pace you can</u> maintain. Ready, Go."					
Start the stop watch when the subject takes their first step. 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. <b>Script: "You're doing a good job. You have completed laps and have to go."</b>					
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).					
<u>After 30 seconds, ask them if they can continue walking.</u> <u>If they can</u> , 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. <u>After another 30 seconds, ask them if they can continue walking.</u> <u>If they can</u> , continue the walk and note the rest stop on the form. (go on to #6) <u>If they cannot continue after a 60 second rest or if they need to sit down, stop the test.</u> (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 television that a cane was used.					
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		LIFE		Acrostic	
Participant ID					Visit
(affix ID label her	.e)				Code
	0)				
When an accelerometer is	s used please	provide the f	ollowing:		
Start Time		Stop Time		Accle	erometer ID#
	ord		record		s of the serial number
time			time in	Last 4 digits	
H H M M a 24			a 24-hr		
clock	()		clock)		
5. Mark an X in the corresp	onding hox w	oon ooch lon	is compl	atad	
5. Mark an X in the corresp		len each lap			
Lap 1 Lap 2 Lap 3	Lap 4			а.	1. Light 2. Somewhat hard
		e tell me ho	w hard v		3. Hard
		re working r			4. Very Hard
	Is it "	light", "som	ewhat h	- u - 122	the participant
	L   "harc	l" or "very h	ard"?	re	ports "hard" or "very
					rd", read script
				be	elow)
- 	Γ		Sorint		to remind you to
<u>Lap 5</u> <u>Lap 6</u> <u>Lap 7</u> <u>L</u>	<u>_ap 8</u> <u>Lap 9</u>	<u>Lap 10</u>			al pace without
			ove	rexerting you	rself. If you
					in or significant
					ath, or are too continue, please
			sto	o walking and	I tell me. If you
					stand in place
			and	rest for a few	v moments.
6. For each rest stop, Mark	an X correspo	onding to the	lenath of	time of the re	est(standing rests only)
				) seconds	
	< 30 sec.	31-60 sec.	(tes	t stopped)	_
Rest stop number 1:					_
Rest stop number 2: Rest stop number 3:					-
Rest stop number 4:					-
Rest stop number 5:					1
Rest stop number 6:					
Rest stop number 7:					4
Rest stop number 8:					-
Rest stop number 9: Rest stop number 10:					-
	Tota	I number of s	tops:		
	. 010				

	LIFE	Acrostic
Participant ID		Visit
(affix ID label here)		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.

Yes

No

8. TIME to walk 400 meters or to stopping the test: Minutes (Interviewer Note: Exclude if > 15 minutes and 0 seconds)

8a. Did the participant use a straight cane during the test?

Seconds

Participant ID

(affix ID label here)

Visit	
Code	

## **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
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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	

	Participant ID (affix ID label here)	LIFE		Visit Code
9. Sitting Radial Pulse: beats per 30 seconds X2 = bpm				
10. If test stopped early, ask: "Why did you feel you couldn't continue?"	10. If test stopped early, ask: "Why	did you feel you cou	uldn't continue?"	3

	Shortness of Breath		Feeling Faint or D	Dizzy
	Chest Pain		Fatigue	
	Leg Pain		Other: (Specify)	
	<sup>:</sup> walk ask, " <b>Is there an</b> please specify what:		ering you?"	Yes No
	Symptoms at end of w		that apply)	
Shortness o Wheezing / Signs of disc	f breath	Unsteadin Sweating		Other:
13. Comment	ts:			

Have the participant complete (i.e. self administer) the Efficacy for Walking instrument immediately following the 400 M Walk at SV1 (or at SV2 if not completed at SV1). At SV1/SV2, the Efficacy for Walking instrument need not be completed if the participant did not finish the 400 M Walk within 15 minutes.