

Entered: __ / __ / 20__ mm dd yy	Initials: _____	Verified: __ / __ / 20__ mm dd yy	Initials: _____
For office use only.			

400 Meter Walk Data Collection Form: Version 12/15/2006

Patient ID ____ - ____ - ____

Form Completion Date __ / __ / 20__
mm dd yy

Certification number: ____

Visit: _____

READ: We would like you to attempt to walk 400 meters (about ¼ mile) at your usual walking pace, as a measure of physical function. So that I can record your heart rate before, during and after the walk I'd like you to wear a Polar heart rate monitor. The monitor has two pieces. The first piece is placed under your shirt against your chest with a band. The second piece, which displays your heart rate, is worn like a wrist watch. Immediately before and after the walk I will measure your heart rate. I will also measure your resting heart rate 2 minutes after you have completed the walk. Therefore, after the walk I will ask you to please sit and rest for 2 minutes. May I put the heart rate monitor on you now?

After putting the Polar Heart Rate Monitor on the participant, accompany the participant to the starting line and ask him or her to sit in the chair at the start while you explain the next section.

During this walk, I will ask you to rate how hard you feel you are working while you continue walking. 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.

Please note, as a safety precaution if your heart rate goes above 135 beats per minute at any time during the walk the heart rate monitor will beep and I will ask you to slow down. Please do not be alarmed, simply slow down. If your heart rate remains above 135 beats per minute for more than 5 minutes I will end the walk and ask that you sit and rest.

If, at any time during the test, you feel any chest pain, tightness or pressure in your chest, you become short of breath or if you feel faint, lightheaded or dizzy, or you feel knee, hip, calf, or back pain please tell me. If you feel any of these symptoms, you may slow down or rest. You may also choose to stop the walk.

Do you have any questions?

1. Resting heart rate before start of walk: _____ bmp

READ: When I say 'GO,' start walking at your **usual pace**. Ready, GO."

Cross off as each lap is completed. If using short course cross off half laps as well.

	1		2		3	4*		5		6		7		8*		9		10
--	---	--	---	--	---	----	--	---	--	---	--	---	--	----	--	---	--	----

Offer participant encouragement after each 40 meter lap.

READ: Good job or you are doing well or keep it up. You have completed ____ laps and have ____ to go.

**After the 4th & 8th lap, read the following question to the participant:*

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

2. Did the participant complete the 4th lap?

☐ 0. No ☐ 1. Yes

2.1 If yes, response after the 4th lap:

- ☐ 1. light
- ☐ 2. somewhat hard
- ☐ 3. hard*
- ☐ 4. very hard*

3. Did the participant complete the 8th lap?

☐ 0. No ☐ 1. Yes

3.1 If yes, response after the 8th lap:

- ☐ 1. light
- ☐ 2. somewhat hard
- ☐ 3. hard*
- ☐ 4. very hard*

**If the participant reports "hard" or "very hard":*

READ: I would like to remind you to walk at your usual pace. 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.

4. Record the following information about rest stops. For each rest stop, record the length of time of the rest (*standing rests only*). After 30 seconds and again after 60 seconds, ask participant if he/she feels okay to continue walking.

Rest Stop	< 30 sec (1)	30 sec (2)	31-59 sec (2)	60 sec (4)	> 60 sec (test stopped) (5)
1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. Total number of rest stops: _____ (*rest stops*)

6. Did participant complete all 10 laps (*short course: count each lap as half lap*)? ☐ 0. No ☐ 1. Yes → Skip to question 7
If no,

6.1 Number of laps completed (*short course: count each lap as half lap*). _____ (*laps*)

6.2 How many additional meters walked after the last fully completed lap? _____ (*meters*)

6.3 Why didn't the participant complete 400 meters (*specify no or yes to each*)?

No	Yes		No	Yes	
<input type="checkbox"/>	<input type="checkbox"/>	Participant reported that they felt too tired	<input type="checkbox"/>	<input type="checkbox"/>	Participant sat down during test
<input type="checkbox"/>	<input type="checkbox"/>	Reported chest pain, tightness, or pressure during test	<input type="checkbox"/>	<input type="checkbox"/>	Participant needed to rest for more than 60 seconds
<input type="checkbox"/>	<input type="checkbox"/>	Reported trouble breathing or shortness of breath during test	<input type="checkbox"/>	<input type="checkbox"/>	Participant requested or needed cane or assistive device
<input type="checkbox"/>	<input type="checkbox"/>	Reported feeling faint, lightheaded or dizzy during test	<input type="checkbox"/>	<input type="checkbox"/>	More than 15 minutes elapsed from start of test
<input type="checkbox"/>	<input type="checkbox"/>	Reported knee pain during test	<input type="checkbox"/>	<input type="checkbox"/>	Participant heart rate was over 135 bmp for 5 minutes
<input type="checkbox"/>	<input type="checkbox"/>	Reported hip pain during test	<input type="checkbox"/>	<input type="checkbox"/>	Participant refused
<input type="checkbox"/>	<input type="checkbox"/>	Reported calf pain during test	<input type="checkbox"/>	<input type="checkbox"/>	Other (Specify: _____)
<input type="checkbox"/>	<input type="checkbox"/>	Reported back pain during test			

7. Time at 400-m or at stop: : :
Min. Sec. Hundredths/Sec

8. Heart rate at 400-m or at stop: _____ bmp

9. Average heart rate at the end of the walk: _____ bmp (*record -2 "n/a" if heart rate was measured manually*)

10. Heart rate 2 minutes after stop: _____ bmp

11. How was heart rate measured for this test? ☐ 1. Polar Heart Monitor ☐ 2. Manually

12. While you were walking did you have any of the following symptoms:

	No	Yes	Don't Know	Refused
12.1 Chest pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.2 Shortness of breath?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.3 Knee pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.4 Hip pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.5 Calf pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.6 Foot pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.7 Numbness or tingling in your legs or feet?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.8 Leg cramps?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.9 Back pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.10 Other (specify _____)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. Are you having any discomfort now? ☐ 0. No ☐ 1. Yes

If yes,

What type of discomfort are you having?	
<p><i>Note: If the participant develops, as a result of the corridor walk, chest pain or other symptoms listed below, the clinic supervisor should be notified immediately to determine whether or not medical attention is warranted. If the participant specifies an "other" symptom, it is up to the person administering the 400 meter walk to determine if a clinic supervisor should be notified to determine whether medical attention is needed. If uncertain, then the clinic supervisor should be notified. A "clinic supervisor" can be any person with medical training who has the ability to determine whether or not there is a need for medical attention prior to the participant leaving the research visit. "Medical attention" is defined as an intervention, prescription for physical therapy, prescription for or administration of medication, medical tests ordered, participant held for observation, etc by a trained medical professional.</i></p>	
	No Yes
13.1 Chest pain, pressure	<input type="checkbox"/> <input type="checkbox"/>
13.2 Shortness of breath	<input type="checkbox"/> <input type="checkbox"/>
13.3 Loss of consciousness or an acute or new-onset bout of "dizziness" and /or "lightheadedness"	<input type="checkbox"/> <input type="checkbox"/>
13.4 Persistent severe lower extremity pain that does not resolve	<input type="checkbox"/> <input type="checkbox"/>
13.5 Wheezing or dyspnea	<input type="checkbox"/> <input type="checkbox"/>
13.6 Other Specify _____	<input type="checkbox"/> <input type="checkbox"/>

400 Meter Walk Form (MWF) QxQ

PURPOSE:	To collect information on patients who complete the 400 meter walk.
PERSON(S) RESPONSIBLE:	Clinician/Coordinator. This is a clinician/coordinator administered form and should NOT be given to the patient to complete.
SOURCES OF INFORMATION:	Observation of patients who complete the 400 meter walk.
WHEN TO ADMINISTER FORM:	After the patient provides informed consent for LABS-2, the MWF form should be administered at the baseline visit and at the 12-month/annual follow up visits.
GENERAL INSTRUCTIONS (Patient)	N/A
GENERAL INSTRUCTIONS: (Clinician)	<p>Before the MWF is completed:</p> <ol style="list-style-type: none"> (1) Read section 8 of the LABS-2 MOP completely and follow the instructions for how to set up the course. (2) Complete the 400 meter eligibility form to assure that the patient is eligible to do the walk. (3) Read section 5 of the LABS-2 MOP that pertains to the use of the Polar Heart Rate Monitor ® to assure the patient is wearing the chest devise and wrist devise correctly. <p>While the MWF is being completed:</p> <ol style="list-style-type: none"> (1) The MWF has scripts that are required to be read aloud while the patient is completing the walk. The scripts are written on the form and should be read verbatim. (2) If the patient needs to stop and rest during the walk or if the patient's heart rate exceeds 135 for more than a period of 5 minutes, follow procedures in Appendix A. <p>After the MWF is completed:</p> <ol style="list-style-type: none"> (1) Clean the Polar Heart Rate Monitor ® as instructed in section 5 of the LABS-2 MOP
SCORING ALGORITHM:	N/A

DATA SECTION	COMPLETION INSTRUCTIONS
PATIENT ID:	<p>Record the patient's ID number. The ID number is assigned via the ID registration application of the MATRIX Web Data Management System (MATRIX). Instructions on using this application are included in the MATRIX Manual. The ID should be written on every page of the MWF form.</p> <p><i>NOTE: The patient ID number is the same as that assigned to the patient as part of the LABS-1 study.</i></p>
FORM COMPLETION DATE:	Record the form completion date as the date in which the form was completed in mm/dd/20yy format.
CERTIFICATION NUMBER:	Record the coordinators certification number. This is the number of the LABS-certified coordinator who is completing the form.
VISIT:	<p>Record the visit number on the form. The visit number corresponds to the anniversary time period of the clinical visit:</p> <p>Baseline = 1 12 month = 12 24 month = 24 36 month = 36</p> <ol style="list-style-type: none"> 1. Record the patient's heart rate before start of walk using the PHRM. <i>Resting is defined as having the patient sit quietly, with feet flat on the floor, in an erect but comfortable posture for at least five minutes, and for at least thirty minutes without smoking or consuming caffeine-containing beverages. See LABS-2 Manual of Operations, under Protocols and Measures for details.</i> 2. Specify whether the patient completed the 4th lap. <ol style="list-style-type: none"> 2.1 If the patient completed the 4th lap, specify the patient's response to how hard he or she is working as either light, somewhat hard, hard, or very hard. <i>NOTE: If the patient reports "hard" or "very hard" the patient should be reminded to walk at a usual pace and if chest pain or significant shortness of breath, or he or she is too uncomfortable to continue, the patient should stop walking.</i> 3. Specify whether the patient completed the 8th lap. <ol style="list-style-type: none"> 3.1 If the patient completed the 8th lap, specify how the patient reported how hard he or she is working as either

light, somewhat hard, hard, or very hard. *NOTE: If the patient reports “hard” or “very hard” the patient should be reminded to walk at a usual pace and if chest pain or significant shortness of breath, or he or she is too uncomfortable to continue, the patient should stop walking.*

4. For each rest stop, record the length of time (as either < 30, 30, 31-59, 60, >60 seconds) the patient had to rest. After 30 seconds and again after 60 seconds, ask the participant if he or she feels okay to continue walking. If the patient does not feel ok to start walking again after 60 seconds, stop the test and have the patient sit down.

If no rest stops are required, record “zero” (0) for question #5

5. Enter the total number of rest stops that the patient took.
6. Specify whether the patient completed all 10 laps. If so, skip to question 7.
- 6.1 Enter the number of laps completed. Record only the number of FULL laps completed.

6.2 Enter how many additional meters the participant walked after the last fully completed lap.

6.3 Specify why the patient did not complete the 400 meters by selecting “no” or “yes” to each of the items as listed on the form.

7. Enter the time when the patient either completed the 400 meters or when he or she needed to stop in minutes, seconds, and hundredths/sec.
8. Record the patient heart rate when the patient either completed the 400 meters or when he or she needed to stop. Ask if the participant needs to sit for a 2 minute recovery period.
9. Record the average heart rate at the end of the walk. Record -2 (n/a) if the heart rate was measured manually.
10. Record the patient's heart rate 2 minutes after the 400 meter walk or when he or she needed to stop. Note, the patient should be seated while the heart rate is measured, but they may stand per their request.
11. Record how the heart rate was measured as either the PHRM or manually.

12. Check either “no” or “yes” as to whether or not the patient has any of the following symptoms:
 - 12.1 Chest pain
 - 12.2 Shortness of breath
 - 12.3 Knee pain
 - 12.4 Hip pain
 - 12.5 Calf pain
 - 12.6 Foot pain
 - 12.7 Numbness or tingling in legs or feet
 - 12.8 Leg cramps
 - 12.9 Back pain
 - 12.10 Other (if other, specify)
13. Ask the patient if he or she is having any discomfort now. “Now” is defined as after the 2 minute heart rate measurement.

If so, ask what type of discomfort the patient is having.
Note: Do NOT read the response options to this question. Mark “no” or “yes” to each. If the patient reports any of the symptoms listed, report to the clinic medical directory immediately. If medical attention is needed as a result of the 400 meter walk, complete an adverse event form.

Items listed:

 - 13.1 Chest pain, pressure
 - 13.2 Shortness of breath
 - 13.3 Loss of consciousness or an acute or new-onset bout of “dizziness and or light headedness
 - 13.4 Persistent severe lower extremity pain that does not resolve.
 - 13.5 Wheezing or dyspnea
 - 13.6 Other (if other, specify)

Appendix A

If the patient feels they need to stop and rest:

If the participant feels they need to stop and rest, they may stand in one place and rest. Also, if the participant appears to be in obvious distress (excessive sweating, unusually pale, labored breathing, unsteady/wavering gait, appears confused, or unresponsive to questions) or pain, you may recommend that he/she stand in place and rest for a moment. After 30 seconds, ask them if they can continue walking. If they can, continue the walk and record the rest on the form. 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 record the rest stop on the form.

If they cannot continue after a 60-second rest or if they need to sit down, stop the test. There is no limit to the number of rest stops as long as they can complete the walk without sitting and within 15 minutes.

If the patient's blood pressure exceeds 135 bpm:

The examiner may initiate a stop if the patient's heart rate exceeds 135 and remains above 135 for more than 5 minutes. The patient's heart rate monitor will emit a short beep to alert you and the patient that the heart rate is out of range. If a participant does not wear the Polar Heart Rate Monitor you will not know if his/her heart rate exceeds 135. Therefore, error on the conservative side and ask the participant to take a break and stand still so you can manually measure his/her heart rate if you suspect it may be too high. As long as the participant does not rest for more than 60 seconds during this break and you feel it is safe, he/she may continue the walk.

If a participant appears short of breath (has difficulty talking while walking) or complains of dizziness, he/she should be asked if he/she feels able to continue to walk. If so, a staff member should walk by the participant at a close distance to prevent falling for the rest of the walk and the patient should be asked about his/her symptoms **every two minutes** for the rest of the walk. Participants may stop the walk at any time, but should not be allowed to lean against any wall or other surface (desk, counter etc.). Staff may stop the walk for evidence of inability to talk while walking, unstable gait, or any other staff concern about the immediate safety of the participant. All participants who exhibit the above symptoms should be escorted to a chair upon stopping the walk and should be guarded when first getting up again.