



TWO MINUTE WALK ELIGIBILITY FORM

ID NUMBER:

FORM CODE:

DATE: 04/06/2022
Version 1.0

ADMINISTRATIVE INFORMATION

0a. Completion Date: / /
Month Day Year

0b. Staff ID:

A. EXCLUSION CRITERIA

Instructions: *Questions in bold and quotes are asked by the examiner of the participant. Question 1 is populated using historical data. Questions 2-4 are answered by CDART or the interviewer, not asked of the participant. Answers to Questions 2-4 will be populated if current visit data is available. If the fields for questions 2-4 are blank, then enter "Yes" or "No". Question 5 is answered by the interviewer, not asked of the participant.*

1. Does the participant have any Ziopatch alert (1a, 1g) for any of the following: wide complex tachycardia >120 bpm sustained for more than 30 seconds or narrow complex tachycardia >180 bpm for 60 seconds or more? [Calculated Script]
2. Is the participant able to complete the 4-meter walk without a walking aid? [Calculated Script]
3. Did the participant have an average resting heart rate between 40-110 bpm today? .. [Calculated Script]
4. Did the participant have a systolic blood pressure >=180 mmHg or diastolic pressure >=120 mmHg today? [Calculated Script]
5. Does the participant currently have a cast or other immobilizing device on leg?.....
Yes 1 **END OF FORM**
No..... 0

Instructions: *Questions in bold and quotes are asked by the examiner of the participant. Question 6 is populated using historical data. If question 6 is "Yes", then question 6a is asked of the participant.*

6. Does the participant have any Ziopatch alert (1b-1e) previously recorded for: 3rd degree (complete) heart block, Mobitz II 2nd degree AV block, pause >6 seconds, or bradycardia <40 bpm and sustained for >30 second?..... [Calculated Script]

"As part of a safety screening process, I would like to ask you a few questions about your medical history."

- a. **"Do you have a pacemaker?"**
Yes 1
No..... 0 **END OF FORM**
Uncertain..... 2 **END OF FORM**

Instructions: *Questions in bold and quotes are asked by the examiner of the participant. Questions 7-8 are asked of the participant. Read the script prior to asking question 7 if not spoken previously.*

“As part of a safety screening process, I would like to ask you a few questions about your medical history.”

7. **“In the past 3 months, have you experienced angina (chest pain due to heart disease), heart attack, angioplasty, or heart surgery?”**

Yes 1 **END OF FORM**
No..... 0

8. **“In the past 3 months, have you seen or thought about seeing a health professional for new or worsening symptoms of chest pain or pressure, shortness of breath, or fainting?”**

Yes 1 **END OF FORM**
No..... 0

Instructions: *Questions in bold and quotes are asked by the examiner of the participant. Question 9a is populated using historical data. If question 9a is “Yes” (participant has history of Atrial Fibrillation) or question 9b is “Yes” (participant has received treatment for Atrial Fibrillation in the past 3 months), then go to Instruction A prior to taking the manual heart rate of the participant.*

History of Atrial Fibrillation:

9. a. Does the participant have history of Atrial Fibrillation? [Calculated Script]

b. **“In the past 3 months, have you received treatment for Atrial Fibrillation?”**.....

Yes 1 **GO TO INSTRUCTION A**
No..... 0 **END OF FORM**

(For 9c) Instruction A:

Read the script: **“I am going to take a manual heart rate. Will you extend your forearm out and have your palm facing up?”** Then complete question 9c.

c. Does the participant have a manual heart rate 40-110 bpm?

Yes 1 **END OF FORM**
No..... 0 **END OF FORM**
Uncertain..... 2 **END OF FORM**

Eligibility for the TMW test will be displayed in the TMW form in item 3a. Save this form and open the TMW form.



INSTRUCTIONS FOR THE TWO MINUTE WALK ELIGIBILITY (TME) FORM

I. General Instructions

The Two Minute Walk Eligibility (TME) Form is completed by the examiner prior to conducting the two minute walk test. See Manual 32 for additional information about safety issues and exclusions for the two minute walk.

The TME is utilized to calculate eligibility for the two minute walk, which is displayed in the Two Minute Walk (TMW) form.

II. Detailed Instructions for Each Item

All items in the TME form address exclusions for the two minute walk. The questions are answered by the following: CDART-generated answers, the examiner, and the participant. If there is a borderline or unclear answer to an exclusion question, then the final decision rests with the medical supervisor.

For items 2, 3, and 4: CDART generates responses for items 2, 3, and 4 if PFX and SBP form data are available. A new TME form must be opened after the PFX and SBP forms are complete. If the data are not available in CDART, then select the “Lock” button to unlock the field and type in the response. **Manual entry of the items 2, 3, and 4 are case sensitive. Valid values for “Yes” responses are [“YES”, “Yes”, or “yes”]; valid values for “No” responses are [“No”, “no”, or “NO”].**

0a-0b. Record the completion date and the staff ID in these fields.

1. This item is system generated in CDART using historical Ziopatch data. If the generated response is “Yes” then save the form and complete the TMW form.
2. This item is system generated in CDART using the Visit 9 PFX form data. If the generated response is “Yes”, then continue to the next item. If the generated response is “No”, then save the form and complete the TMW form.

If there are no PFX data available in CDART, then use information from the 4-meter walk paper form. If the participant did not use a walking aid, record response as “Yes”. If the participant used a walking aid, record response as “No” then save the form and complete the TMW form.

Note: Some participants who complete the short walks without a walking aid may be uncomfortable and/or unwilling to attempt a longer walk, such as the two minute walk, without the walking aid.

3. This item is system generated in CDART using the Visit 9 SBP form data. If the generated response is “Yes”, then continue to the next item. If the generated response is “No”, then save the form and complete the TMW form.

If there are no SBP data available in CDART, then consult the heart rate from the clinic exam. If the average heart rate was between 40 to 110 *inclusive* bpm, record response as “Yes”. If the average heart rate was outside of the range 40-110 bpm, record response as “No” then save the form and complete the TMW form.

- Example 1: if the participant’s average heart rate is 40, record response as “Yes”.

- Example 2: if the participant's average heart rate is 39, record response as "No". Then save the TME form and complete the TMW form.
4. This item is system generated in CDART using the Visit 9 SBP form data. If the generated response is "No", then continue to the next item. If the generated response is "Yes", then save the form and complete the TMW form
 If there are no SBP data available in CDART, then consult the blood pressure values from the clinic exam. If the systolic blood pressure was ≥ 180 or the diastolic blood pressure was ≥ 120 , record response as "Yes" then save the form and complete the TMW form.
 5. If the participant has a cast, brace, or other immobilizing device on his/her leg, record "Yes" then save the form and complete the TMW form.
 6. This item is system generated in CDART using historical Ziopatch data. If the generated response is "Yes," then proceed to question 6a.
 - a. Read the Script: **"I would like to ask you a few questions about your medical history."** Then, **read the question as written.** Fill in the participant's response to question 6a. If the response is "No" or "Uncertain", then save the form and complete the TMW form.

Read the Script: **"I would like to ask you a few questions about your medical history."**

7. **Read the question as written.** Fill in the participant's response to question 7. If the response is "Yes", then save the form and complete the TMW form.
8. **Read the question as written.** Fill in the participant's response to question 8. If the response is "Yes", then save the form and complete the TMW form.
- 9a. This item is system generated by CDART using sources of Atrial Fibrillation data listed in Manual 32. If the generated response is "Yes", then go to Instruction A and proceed to question 9c. If the generated response is "No", then proceed to question 9b.
- 9b. **Read the question as written.** If the participant is unsure or does not recall an atrial fibrillation event, then explain to the participant that atrial fibrillation is an abnormal, irregular rhythm of the heart (arrhythmia) that often requires medicines or medical procedures to treat the condition. It is sometimes called "Afib" for short.
 Fill in the participant's response to question 9b. If the response is "Yes", then go to Instruction A and proceed to question 9c. If the response is "No", then save the form and complete the TMW form.
- 9c. Review the instructions for measuring manual heart rate as described in section 3.2 of Manual 32. Then read the script in Instruction A prior to taking the manual heart rate of the participant.

Record "Yes" if the 20-second heart rate is between 14-36 beats.

Record "No" if the 20-second heart rate is < 13 or > 37 beats.

Record "Uncertain" if the 20-second heart rate is uncertain due to a weak or irregular pulse. Indicate the reason for uncertainty of participant's heart rate in a notelog.

Save the form and complete the TMW form.