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 <u>after</u> the PFX and SBP forms are complete. Then, the 'Save and Reload' button must be selected to populate current visit data. 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.

Click 'Save and Reload' to populate current visit data before proceeding to items 2, 3, and 4.

2. This item is system generated in CDART using the Visit 11 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.

    *The 4-meter walk **must** take place on the same day as the TME/TMW. Review Manual 32, 5.2. Safety Issues and Exclusions for the Two Minute Walk, for more information on using PFX form data for ARIC participants and ACHIEVE-enrolled participants.

    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 11 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 11 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.