



SV1

ID: _____
Date: ___/___/___

Rose Questionnaire – PVD

- | | Yes | No |
|--|---|---|
| 1. In the past month , have you had a pain in either leg on walking?..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2
↓
Stop |
| 2. Does this pain ever begin when you are standing still or sitting?..... | <input type="checkbox"/> 1
↓
Stop | <input type="checkbox"/> 2 |
| 3. Do you get this pain in your calf (or calves)?..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2
↓
Stop |
| 4. Do you get it when you walk uphill or hurry? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2
↓
Stop |
| 5. Do you get it when you walk at an ordinary pace on the level? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 6. Does the pain ever disappear while you are still walking?..... | <input type="checkbox"/> 1
↓
Stop | <input type="checkbox"/> 2 |
| 7. What do you do if you get it when you are walking? | Stop or Slow Down <input type="checkbox"/> 1 | Continue at same pace <input type="checkbox"/> 2
↓
Stop |
| 8. What happens to it if you stand still?..... | Usually disappears in 10 minutes or less <input type="checkbox"/> 1 | Usually continues more than 10 minutes <input type="checkbox"/> 2 |

Office use

9. Outcome: *Positive 1
Negative 2

* If positive, refer to clinician and complete follow up worksheet.

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Rose Questionnaire-PVD

Overview

The purpose of this interviewer-administered form is to identify individuals with peripheral vascular disease. This form may be self administered if it is thoroughly explained to the participant. If it is self-administered, it is suggested that the first question be interviewer-administered, and the questionnaire only handed out to participants who answer “Yes” to the first question.

The form will be used at SV1 to identify participants with suspected peripheral vascular disease who need physician approval to continue in the study. When uncertainty remains after reviewing a question with these instructions, please indicate this on the questionnaire and send to the study clinician for review.

Administration Instructions

Using a blue or black pen, fill out the visit date on page 1. Be sure to use a four digit year.

Place ID label on page 1.

This form should be completed by the interviewer due to its complexity, but can be self administered if thoroughly explained to the participant.

<u>Page</u>	<u>Question</u>	<u>Special Administration Instructions (if any)</u>
1	1	If Yes, Q2 should be completed. If No, Stop.
	2	If Q1 = “Yes“, this question may not be left blank. If Yes, Stop. If No, Q3 should be completed.
	3	If Q1 = “Yes” and Q2 = “No”, this question may not be left blank. If Yes, Q4 should be completed. (A “Yes” response may include other leg pain, but <u>must</u> include pain in at least <u>one</u> calf.) If No, Stop.
	4	This question refers to pain without exceptional exertion. If both Q1 and Q3 = “Yes” <u>and</u> Q2 = “No”, this question may not be left blank. If Yes, Q5 should be completed. If No, Stop. (Clarify all “No” responses. If “No” is marked because they <u>don’t</u> walk uphill or hurry, restate the question: “If you did walk up hill or hurry, do you think it would cause pain in either leg?”)
	5	If Q1, Q3, and Q4 all = “Yes” <u>and</u> Q2 = “No“, this question may not be left blank. Q6 should be completed regardless of the response selected in Q5. This question is to be used by the study clinician to help determine severity. It is not used in determining outcome.
	6	If Q1, Q3 and Q4 all = “Yes”, <u>and</u> Q2 = “No”, this question may not be left blank. If “Yes”, Stop. If “No”, Q7 should be completed.
	7	If Q1, Q3, and Q4 all = “Yes,” <u>and</u> both Q2 and Q6 = “No”, this question may not be left blank. If answer is “Stop or Slow down”, Q8 should be completed. If answer is “Continue at same pace”, Stop.

<u>Page</u>	<u>Question</u>	<u>Special Administration Instructions (if any)</u>
1	8	If Q1, Q3, and Q4 all = “Yes,” both Q2 and Q6 = “No” <u>and</u> Q7 = “Stop or Slow Down“, this question may not be left blank.
	9	Should be filled out for all participants. If participant reached a “Stop” outcome above or Q8 = “Usually continues more than 10 minutes” enter “Negative”. If you have gotten to this point without reaching a “Stop” and Q8 = “Usually disappears in 10 minutes or less“, enter “Positive” and complete the Positive PVD worksheet.

Coding Instructions

Make sure all corrections are initialed and dated with an explanation.

When filling out the “Reviewed by” and “Entered by” box, be sure to use the correct staff ID number. The “Entered by” staff ID number should not be filled in until the form is entered.

Review Instructions

If the participant is Negative for PVD (Q9 = Negative), confirm that a “Stop” outcome occurred on the form or Q8 = “Usually continues more than 10 minutes“, enter “Negative” on the SV1 Visit Form (#03) for the Rose Questionnaire-PVD outcome.

If the participant is Positive for PVD (Q9 = Positive), all of the following conditions must be met:

- Q1 = Yes
- Q2 = No
- Q3, and Q4, = Yes
- Q6 = No
- Q7 = “Stop or Slow Down”
- Q8 = “Usually disappears in 10 minutes or less“,

When all the above conditions are met (Q9 = Positive), staff must complete the Positive PVD screening worksheet.

If all of the above items look acceptable, enter your Staff ID number in the “reviewed by” section at the bottom of page 1, and enter “Positive” on the SV1 Visit Form (#03) for the Rose Questionnaire-PVD outcome.

Additional Instructions

Need to write up instructions about how clinician should review form.

Positive PVD Worksheet

This worksheet is to be completed for every participant who is coded as POSITIVE on Q9 of the Rose Questionnaire – PVD.

Steps for all participants

- Refer the participant to their personal physician. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. If they do not have a personal physician, help them to find a physician.

Referral Date: _____

Physician Name (if known): _____

Physician Phone (if known): _____

- Confirm participant saw physician: (circle one) CONFIRMED / UNABLE TO CONFIRM
- Does participant wish to continue in the trial? (circle one) YES / NO
(If YES, then go on to the following section. If NO, close the participant out as a “Refusal” on the visit form or on a closeout form if between visits).

Steps for participants who wish to continue in the trial:

- Contact participant’s physician to get approval for participation in the study. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician.

Physician Name: _____

Physician Phone: _____

Date of contact: _____

Outcome of contact (circle one): EXCLUDE / OK TO CONTINUE*

Notes: _____

- Study clinician reviews study chart

Study Clinician Name: _____

Date of Review: _____

Outcome of review (circle one): EXCLUDE / OK TO CONTINUE*

Study Clinician Signature: _____

Notes: _____

**Participant can only continue if form is determined to be a false positive.*

(If both the participant’s physician and the study clinician say the participant is “OK to continue,” enter an outcome of “Eligible” on the Pre-Randomization Checklist. Otherwise, enter “Ineligible.” To close the participant out prior to completing the Pre-Randomization Checklist, you can enter a closeout form with the reason coded as “Investigator discretion for safety”)