



SV1  
ID: \_\_\_\_\_

### SV1 Visit Form

**DONE?**

- Check visit window (≤4 months since PSV).....
- Informed consent (if applicable) .....
- Participant contact information sheet.....

- Complete SV1 Blood Pressure Form ..... **eligible**  1  
**ineligible**  2
- Complete Eligibility Questionnaire..... **eligible**  1  
(including clinician review if necessary) **ineligible**  2

**DONE?**

- Review SV1/SV2 Activity Fact Sheet.....
- Complete Diet and Physical Activity Change Checklist ..... **eligible**  1  
**ineligible**  2

Measure height and weight

Height \_\_\_\_\_ . \_\_\_\_\_ cm

Weight \_\_\_\_\_ lbs ..... **eligible**  1  
**ineligible**  2

- Complete Rose Questionnaire – PVD ..... **positive\***  1  
**negative**  2
- Complete Rose Questionnaire – Angina ..... **positive\***  1  
**negative**  2

- SV1 Visit Outcome ..... **eligible**  1  
**ineligible**  2  
**refused**  3

SV2 Visit Date: \_\_\_\_\_  
(remind participant to bring in medications for SV2)

\*Requires physician followup prior to randomization.

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

# SV1 Visit Form Training Manual and Coding Instructions

## Overview

The SV1 Visit form is filled out by clinic staff and is used to track the progress of the participant through the components that make up the SV1 visit.

As soon as a participant is determined to be ineligible, check the “Ineligible” box under the Visit Outcome and terminate the visit. If a participant refuses to complete the visit, check the “Refused” box under the Visit Outcome and terminate the visit. For eligible participants, all items must be completed.

Do not enter this form until the visit is complete and a final outcome is determined. If visit is incomplete and will not be completed, either enter “Refused” (if appropriate), or close out the participant using the closeout form and do not enter the visit form.

## Administration Instructions

Using a blue or black pen, fill out each of the items on page 1. If a participant becomes ineligible at any point, you do not need to complete the remaining items.

<b><u>Question</u></b>	<b><u>Special Administration Instructions (if any)</u></b>
Check visit window	Make sure that no more than 4 calendar months have elapsed since the PSV visit date. If more than 4 months have elapsed, repeat the PSV visit.
Informed consent	The need for a consent to be done at a specific visit will vary by site. If consent is being done at this visit, check the “Done?” box.
Participant information	After completing form #100, the Participant Information Sheet, check the “Done?” box.
SV1 BP Form	After completing form #2, enter the eligibility outcome. If ineligible, skip to the SV1 Outcome field, check the “ineligible” box, and terminate the visit.
Eligibility Questionnaire	After completing form #4, enter the eligibility outcome. If ineligible, skip to the SV1 Outcome field, check the “ineligible” box, and terminate the visit.
Review fact sheet	After reviewing form #106 with the participant, check the “Done?” box. If the participant decides after reviewing the fact sheet that they do not wish to continue with the study, skip to the SV1 Outcome field, check the “refusal” box, and terminate the visit.
Checklist	After participant completes form #8, enter the eligibility outcome.
Height	Measure the participant’s height in centimeters following the procedures in Chapter 20 (Other Clinical Measures). Record the result, rounding to the nearest 0.1 cm.

<u>Question</u>	<u>Special Administration Instructions (if any)</u>
Weight	Measure the participant's weight in pounds following the procedures in Chapter 20 (Other Clinical Measures). Record the result, rounding to the nearest 0.25 lb.
Rose PVD	After completing form #5, enter the positive or negative outcome. For this form, either a positive or a negative outcome makes the participant eligible to continue. If positive and your investigator chooses to exclude the participant without further followup, this must be done with a closeout form, do not check the "ineligible" box on this form.
Rose Angina	After completing form #6, enter the positive or negative outcome. For this form, either a positive or a negative outcome makes the participant eligible to continue. If positive and your investigator chooses to exclude the participant without further followup, this must be done with a closeout form, do not check the "ineligible" box on this form.
BMI Outcome	Use height and weight to compute BMI outcome. See Coding Instructions below
SV1 Visit Outcome	see Coding Instructions below

### **Coding Instructions**

**BMI outcome:** Using the attached SV1 BMI Reference chart, look up the participant's height. Round off decimals for height (i.e. 150.4 rounds to 150, 150.5 rounds to 151) when looking up heights in the table. If the participant's weight is between the minimum and maximum in the table, check the "eligible" box, otherwise, check the "ineligible" box.

**SV1 Visit Outcome:** After all other items are complete, enter the visit outcome. If the outcomes for blood pressure, Eligibility Questionnaire, Diet and Physical Activity Change Checklist, and BMI are all "eligible" and the participant wishes to continue, check the "eligible" box. If any item is marked "ineligible," check the "ineligible" box. If the participant refused at any point, check the "refusal" box. If visit is incomplete and will not be completed, either enter "Refused" (if appropriate), or close out the participant using the closeout form and do not enter the visit form.

### **Review Instructions**

Do not review this form until the visit is complete and a final outcome is determined.

If visit is incomplete and will not be completed, either enter “Refused” (if appropriate), or close out the participant using the closeout form and do not enter the visit form. For all participants:

- Make sure that the ID label has been attached.

For eligible participants:

- Check that all items have been completed.
- Make sure that all of the eligible/ineligible responses have been checked “eligible.”

For ineligible participants:

- All items do not have to be completed, but make sure that at least one eligible/ineligible response has been checked “ineligible.”

For refusals:

- No other items are required.

After reviewing the form, enter your staff ID on the “Reviewed by” line.

### **Additional Instructions**

Do not enter this form until:

- the visit is complete
- a final outcome is determined
- all other forms related to the visit (#2, 4, 5, 6) have been entered. (Form #106 is not entered)

If either Rose Questionnaire had a positive outcome, and the SV1 Outcome is “eligible,” be sure to begin the process of contacting the participant’s physician to get permission for the subject to participate in the trial. This process must be completed before the participant can be randomized.

**SV1 BMI Reference Chart (minimum BMI=18.5, maximum BMI=45)**

*(round off decimals for height: 150.4 rounds to 150, 150.5 rounds to 151)*

Height in	Weight in lbs	
	Min weight	Max Weight
139	78.00	194.25
140	79.00	197.00
141	80.25	199.75
142	81.25	202.75
143	82.50	205.50
144	83.75	208.50
145	84.75	211.25
146	86.00	214.25
147	87.25	217.25
148	88.50	220.25
149	89.50	223.25
150	90.75	226.00
151	92.00	229.25
152	93.25	232.25
153	94.50	235.25
154	95.75	238.25
155	97.00	241.50
156	98.25	244.50
157	99.50	247.75
158	100.75	250.75
159	102.00	254.00
160	103.25	257.25
161	104.75	260.50
162	106.00	263.75
163	107.25	267.00
164	108.50	270.25
165	110.00	273.50
166	111.25	276.75
167	112.50	280.25
168	114.00	283.50
169	115.25	286.75
170	116.75	290.25
171	118.00	293.75
172	119.50	297.00
173	120.75	300.50
174	122.25	304.00
175	123.75	307.50
176	125.00	311.00

Height in	Weight in lbs	
	Min weight	Max Weight
177	126.50	314.50
178	128.00	318.25
179	129.50	321.75
180	130.75	325.25
181	132.25	329.00
182	133.75	332.50
183	135.25	336.25
184	136.75	340.00
185	138.25	343.50
186	139.75	347.25
187	141.25	351.00
188	142.75	354.75
189	144.25	358.50
190	145.75	362.50
191	147.50	366.25
192	149.00	370.00
193	150.50	374.00
194	152.00	377.75
195	153.75	381.75
196	155.25	385.50
197	156.75	389.50
198	158.50	393.50
199	160.00	397.50
200	161.75	401.50
201	163.25	405.50
202	165.00	409.50
203	166.50	413.50
204	168.25	417.75
205	169.75	421.75
206	171.50	425.75
207	173.25	430.00
208	174.75	434.25
209	176.50	438.25
210	178.25	442.50
211	180.00	446.75
212	181.75	451.00
213	183.25	455.25
214	185.00	459.50