

Baseline/Randomization Visit: Patient Characteristics Form Instructions
RPC Version B: 3/03/2005
QxQ Date: 03/02/2005

I. GENERAL INSTRUCTIONS

The Baseline/Randomization Visit: Patient Characteristics Form (RPC) is completed during the Screening/Baseline Combination Visit or the Randomization Clinic Visit. It is used to obtain baseline information including: blood pressures, smoking, medical, dietary and physical activity history. For further information on the randomization process refer to the Randomization Visit Chapter in the Manual of Procedures, Chapter 4.

Interviewers must be familiar with and understand the Administration Procedures Chapter in the Manual of Procedures, Chapter 14, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTION

A. Clinic Examination

Blood pressure will be taken twice during this visit, and should be taken from the right arm (preferably), while the participant is seated. Continuing through the questions following the first blood pressure will allow adequate time between the first and second readings, but at least 5 minutes must elapse. If for some reason it is not possible to obtain blood pressure measurements from either right or left arm, enter equal signs in the relevant fields; leg pressures may **not** be substituted.

1. Seated Blood Pressure #1:
 - a. Record the participant's systolic blood pressure filling in the fields using leading zeroes where necessary.
 - b. Record the participant's diastolic blood pressure, filling in the fields using leading zeroes where necessary.
 - c. Indicate on which arm the blood pressure was taken by circling "R" for right or "L" for left.
2. Obtain the height with shoes removed. Record the height in inches; if using a scale with centimeters, divide centimeters by 2.54 to obtain inches, filling in the fields using leading zeroes where necessary. If necessary, round to the nearest inch.

The following guidelines have been approved by the FAVORIT Executive Committee for the Measurement of Height of Amputees or Wheelchair-bound participants:

For a bilateral amputee, height should be missing data. Participants with unilateral amputations or confined to a wheelchair should be supported and their height measured. If this is not possible, height becomes missing data.

3. Obtain weight in street clothes with shoes removed. Record the weight in pounds; if using a scale with kilograms, divide kilograms by 0.45, filling in the fields using leading zeroes where necessary. For fractional weights, round to the nearest whole pound.

The following guidelines have been approved by the FAVORIT Executive Committee for the Measurement of Weight of Amputees or Wheelchair-bound participants:

Weight should be obtained by using an available scale in the clinic or hospital. Self-reported weight should not be used. Weight should be body weight without prostheses. If weight must be taken with prostheses, obtain weight and then subtract the weight of the prostheses.

4. The DMS will automatically calculate the body mass index (BMI); you do not have to calculate the BMI manually. If the BMI is greater than or equal to 40 the Study Coordinator must notify the participant's primary care physician and inform him/her of this information

B. Smoking History

5. The smoking history questions focus on current or former cigarette smoking (cigar or chewing tobacco is excluded), duration, intensity, and length of time since quitting. Currently refers to at least one cigarette per day on average over the past month.
 - a. Indicate smoking status by circling "A" if the participant never smoked and go to item 7; circle "B" if the participant is a current smoker (i.e. if s/he smokes at least one cigarette a day on average during the past month) and continue to the next item; or circle "C" if the participant has ever smoked but is not currently smoking (i.e., former smoker) and go to item 6.
 - b. Items 5 b and c are to be completed if the patient is a current smoker. Record the total number of years the participant has smoked, filling in the fields using leading zeroes where necessary.
 - c. Record the average number of cigarettes currently (over the past month) smoked per day, using leading zeroes where necessary and go to item 7.
6. Items 6a-d are to be completed **only** by former smokers.
 - a-b Record how many years and months the participant has quit smoking, since his/her most recent date of quitting smoking, filling in the fields using leading zeroes where necessary.

- c. Record how many cigarettes were smoked per day on average, filling in the fields using leading zeroes where necessary.
- d. Record the total number of years the participant smoked, filling in the fields using leading zeroes where necessary.

C. Medical History

- 7. Record any evidence of cardiovascular disease (CVD) history or procedures. Circle “M” if according to the participant’s medical record/chart the participant received any of the diagnoses and/or procedures. Otherwise, circle “P” if they received any of the diagnoses and/or procedures and the information is obtained from the participant. Circle “N” if the participant did **not** receive any of the diagnoses and/or procedures.
 - a. Record history of myocardial infarction/heart attack.
 - b. Record history of coronary artery revascularization, (CABG or angioplasty).
 - c. Record history of stroke, either atherothrombotic or hemorrhagic.
 - d. Record history of carotid arterial revascularization (endarterectomy or angioplasty).
 - e. Record history of abdominal aortic aneurysm (AAA) or thoracic aneurysm repair.
 - f. Record history of renal arterial revascularization (bypass or angioplasty).
 - g. Record history of lower extremity arterial revascularization (bypass or angioplasty).
 - h. Record history of lower extremity amputation above the ankle.
- 8. Record history of diabetes, not differentiating between Type I and Type II. Circle “M” if the information is from the medical record/chart, “P” if it is from the participant and “N” if they have **not** been diagnosed with diabetes. Previously diabetic participants who have received a pancreatic transplant are considered as diabetic.

D. Dietary Interview

The dietary questions are designed to document regular intake of heavily fortified cereals, and/or liquid/powdered dietary supplements that contain large amounts of folic acid per serving.

9. If the participant has consumed a one cup serving of cold cereal at least 3 times per week over the last 3 months record “Yes” and continue to the next item. If they have not then record “No” and go to item 11.
10. a-h. For each of the cereals listed in *a* through *h* record “Yes” if the participant has eaten one cup at least 3 times per week. Record “No” if they have not eaten at least one cup 3 times per week. The cereals are grouped by brand name, then listed individually. It is very important that both the brand name and the type of cereal be read, since only these specific ones are highly fortified. If the participant responds that he/she has eaten one-cup servings from three or more of the listed cereals, record “Yes” for each listed cereal that was consumed.
11. If the participant has consumed 8 ounces of liquid or powdered dietary supplement at least 3 times per week over the last 3 months record “Yes” and continue to the next item. If they have not then record “No” and go to item 13.
12. a-g. For each of the liquid or powdered dietary supplements listed in *a* through *e* record “Yes” if the participant has drunk 8 ounces at least 3 times per week. Record “No” if they have not drunk at least 8 ounces at least 3 times a week. If the participant drank any other supplement that is not listed in a-e then record “Yes” on item f and specify the name of the supplement in item g. Otherwise, record “No” on item f and go to item 13.

E. Physical Activity Interview

The physical activity questions ask about the participant’s activities during the past month. All activities are graded according to intensity and/or duration. The activities may be part of work, household tasks or leisure. Seven response cards are provided by the DCC to be shown to the participant while you are reading the responses. This allows him/her to more easily remember the options for each item. The DCC will calculate a physical activity summary score based on the raw data.

13. This question pertains to vigorous activity that the participant has participated in the during the past month that lasted at least 10 minutes and caused increases in breathing, heart rate, leg fatigue, or perspiration. Show Card #1 to the participant, then read the responses, ask the participant to choose one of the responses, A through E, and record their answer. If s/he chooses “A. Not at all”, go to item 15 otherwise continue to the next item. It does not matter what the activity was as long as it caused increases in breathing, heat rate, leg fatigue or perspiration.

14. This question pertains to the average duration of the vigorous activities. Show Card #2 to the participant, then read the responses, ask the participant to choose one of the responses A through C, and record their answer.
15. This question pertains to leisurely walks the participant has taken during the past month that lasted at least 10 minutes and were not strenuous. Show Card #3 to the participant, then read the responses, ask the participant to choose one of the responses, A through E, and record their answer. If s/he chooses "A. Not at all", go to item 17 otherwise continue to the next item. As long as the walks were approximately 10 minutes in length and were continues (without stopping) it does not matter where the walks occurred.
16. This question pertains to the average duration of the walk. Show Card #4 to the participant, then read the responses, ask the participant to choose one of the responses, A through C, and record their answer.
17. This question pertains to how many hours the participant spends moving about on his/her feet on a typical day during the past month. Show Card #5 to the participant, then read the responses, ask the participant to choose one of responses, A through F, and record their answer.
18. This question pertains to how much time the participant spends standing or moving around on his/her feet during the past month. Show Card #6 to the participant, then read the responses, as the participant to choose one of responses, A through F, and record their answer.
19. This question pertains to how many hours were spent sitting daily on a typical day in the past month. Show Card #7 to the participant, then read the responses, ask the participant to choose one of the responses, A through E, and record their answer.
20. Record the number of flights of stairs that the participant climb up on a daily bases during the past month, use leading zeroes when necessary. Steps walked down do not count.

F. Second Blood Pressure

21. Seated Blood Pressure #2: The arm used for the first blood pressure is the preferred arm to be used for the second blood pressure.
 - a. Record the participant's second seated systolic blood pressure filling in the fields using leading zeroes where necessary.
 - b. Record the participant's second seated diastolic blood pressure filling in the fields using leading zeroes where necessary.
 - c. Indicate on which arm the blood pressure was taken by circling "R" for right or "L" for left.

22. a-b. The average systolic and diastolic blood pressure is calculated automatically by the DMS. If the average systolic value is between 180 mmHg and 199 mmHg (or higher) the participant's primary care physician should be notified. If the average systolic value is greater than or equal to 200 mmHg the participant must be seen immediately by a physician. If the average diastolic value is between 100 mmHg and 109 mmHg (or higher) the participant's primary care physician should be notified. If the average diastolic value is greater than or equal to 110 mmHg the participant must be seen immediately by a physician.

G. Administrative Information

23. Record the date of data collection, using the U.S. order (month/day/year). Code numbers using lead zeros when necessary to fill in all fields. For example, May 6, 2002 would be recorded as 05/06/2002.

24. Record whether the data was collected directly into the data entry system on the computer or whether it was recorded on a paper form.

25. Record whether this is a screening/baseline combination visit.

26. Enter the data collector's initials using the 3 initials of the person completing this form. If he/she only has two initials, then record the 1st name initial in the first box, the last name initial in the 2nd box and leave the third box blank.

Upon completion of this form proceed to the Baseline/Randomization/Follow-Up Phlebotomy Collection Form and schedule the participant for both the 6 month phone follow-up and the 12 month clinic visit.

Randomization Visit: Patient Characteristics Form Instructions
RPC Version A: 3/15/2002
QxQ Date: 6/10/2002

I. GENERAL INSTRUCTIONS

The Randomization Visit: Patient Characteristics Form (RPC) is used to obtain baseline information including: blood pressures, smoking, medical, dietary and physical activity history. For further information on the randomization process refer to the Randomization Visit Chapter in the Manual of Procedures, Chapter 4.

Interviewers must be familiar with and understand the Administration Procedures Chapter in the Manual of Procedures, Chapter 14, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTION

A. Clinic Examination

Blood pressure will be taken twice during this visit, and should be taken from the right arm (preferably), while the participant is seated. Continuing through the questions following the first blood pressure will allow adequate time between the first and second readings, but at least 5 minutes must elapse. If for some reason it is not possible to obtain blood pressure measurements from either right or left arm, enter equal signs in the relevant fields; leg pressures may **not** be substituted.

1. Seated Blood Pressure #1:
 - a. Record the participant's systolic blood pressure filling in the fields using leading zeroes where necessary.
 - b. Record the participant's diastolic blood pressure, filling in the fields using leading zeroes where necessary.
 - c. Indicate on which arm the blood pressure was taken by circling "R" for right or "L" for left.
2. Obtain the height with shoes removed. Record the height in inches; if using a scale with centimeters, divide centimeters by 2.54 to obtain inches, filling in the fields using leading zeroes where necessary. If necessary, round to the nearest inch.
3. Obtain weight in street clothes with shoes removed. Record the weight in pounds; if using a scale with kilograms, divide kilograms by 0.45, filling in the fields using leading zeroes where necessary. For fractional weights, round to the nearest whole pound.

4. The DMS will automatically calculate the body mass index (BMI); you do not have to calculate the BMI manually. If the BMI is greater than or equal to 40 the Study Coordinator must notify the participant's primary care physician and inform him/her of this information

B. Smoking History

5. The smoking history questions focus on current or former cigarette smoking (cigar or chewing tobacco is excluded), duration, intensity, and length of time since quitting. Currently refers to at least one cigarette per day on average over the past month.
 - a. Indicate smoking status by circling "A" if the participant never smoked and go to item 7; circle "B" if the participant is a current smoker (i.e. if s/he smokes at least one cigarette a day on average during the past month) and continue to the next item; or circle "C" if the participant has ever smoked but is not currently smoking (i.e., former smoker) and go to item 6.
 - b. Items 5 b and c are to be completed if the patient is a current smoker. Record the total number of years the participant has smoked, filling in the fields using leading zeroes where necessary.
 - c. Record the average number of cigarettes currently (over the past month) smoked per day, using leading zeroes where necessary and go to item 7.
6. Items 6a-d are to be completed **only** by former smokers.
 - a-b Record how many years and months the participant has quit smoking, since his/her most recent date of quitting smoking, filling in the fields using leading zeroes where necessary.
 - c. Record how many cigarettes were smoked per day on average, filling in the fields using leading zeroes where necessary.
 - d. Record the total number of years the participant smoked, filling in the fields using leading zeroes where necessary.

C. Medical History

7. Record any evidence of cardiovascular disease (CVD) history or procedures. Circle "M" if according to the participant's medical record/chart the participant received any of the diagnoses and/or procedures. Otherwise, circle "P" if they received any of the diagnoses and/or procedures and the information is obtained from the participant. Circle "N" if the participant did **not** receive any of the diagnoses and/or procedures.

- a. Record history of myocardial infarction/heart attack.
 - b. Record history of coronary artery revascularization, (CABG or angioplasty).
 - c. Record history of stroke, either atherothrombotic or hemorrhagic.
 - d. Record history of carotid arterial revascularization (endarterectomy or angioplasty).
 - e. Record history of abdominal aortic aneurysm (AAA) or thoracic aneurysm repair.
 - f. Record history of renal arterial revascularization (bypass or angioplasty).
 - g. Record history of lower extremity arterial revascularization (bypass or angioplasty).
 - h. Record history of lower extremity amputation above the ankle.
8. Record history of diabetes, not differentiating between Type I and Type II. Circle “M” if the information is from the medical record/chart, “P” if it is from the participant and “N” if they have **not** been diagnosed with diabetes. Previously diabetic participants who have received a pancreatic transplant are considered as diabetic.

D. Dietary Interview

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11. If the participant has consumed 8 ounces of liquid or powdered dietary supplement at least 3 times per week over the last 3 months record “Yes” and continue to the next item. If they have not then record “No” and go to item 13.

12. a-g. For each of the liquid or powdered dietary supplements listed in *a* through *e* record “Yes” if the participant has drunk 8 ounces at least 3 times per week. Record “No” if they have not drunk at least 8 ounces at least 3 times a week. If the participant drunk any other supplement that is not listed in a-e then record “Yes” on item f and specify the name of the supplement in item g. Otherwise, record “No” on item f and go to item 13.

E. Physical Activity Interview

The physical activity questions ask about the participant’s activities during the past month. All activities are graded according to intensity and/or duration. The activities may be part of work, household tasks or leisure. Six response cards are provided by the DCC to be shown to the participant while you are reading the responses. This allows him/her to more easily remember the options for each item. The DCC will calculate a physical activity summary score based on the raw data.

13. This question pertains to vigorous activity that the participant has participated in the during the past month that lasted at least 10 minutes and caused increases in breathing, heart rate, leg fatigue, or perspiration. Show Card #1 to the participant, then read the responses, ask the participant to choose one of the responses, A through E, and record their answer. If s/he chooses “A. Not at all”, go to item 15 otherwise continue to the next item. It does not matter what the activity was as long as it caused **increases in breathing, heart rate, leg fatigue or perspiration.**
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17. This question pertains to how many hours the participant spends moving about on his/her feet on a typical day during the past month. Show Card #5 to the participant, then read the responses, ask the participant to choose one of responses, A through F, and record their answer.
18. This question pertains to how many hours were spent sitting daily on a typical day in the past month. Show Card #6 to the participant, then read the responses, ask the participant to choose one of the responses, A through E, and record their answer.

19. Record the number of flights of stairs that the participant climb up on a daily bases during the past month, use leading zeroes when necessary. Steps walked down do not count.

F. Second Blood Pressure

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G. Administrative Information

22. Record the date of data collection, using the U.S. order (month/day/year). Code numbers using lead zeros when necessary to fill in all fields. For example, May 6, 2002 would be recorded as 05/06/2002.
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