

Baseline/Randomization Visit Form: Patient Characteristics (RPCB Screen 3 of 14)

C. Medical History

7. Has the patient ever received any of the following cardiovascular disease-related diagnoses, and/or undergone any of the following cardiovascular disease-related procedures? [If yes, indicate the documentation source-preferably Medical Record/Chart Review.]

	<u>Yes, Medical Record/Chart Review</u>	<u>Yes, Patient Report Only</u>	<u>No</u>	
a. Myocardial infarction	M	P	N	RPC7A
b. Coronary artery revascularization (i.e., coronary artery bypass surgery or angioplasty)	M	P	N	RPC7B
c. Stroke (atherothrombotic or hemorrhagic)	M	P	N	RPC7C

Baseline/Randomization Visit Form: Patient Characteristics (RPCB Screen 4 of 14)

7. Has the patient ever received any of the following cardiovascular disease-related diagnoses, and/or undergone any of the following cardiovascular disease-related procedures? [If yes, indicate the documentation source-preferably Medical Record/Chart Review.]

	<u>Yes, Medical Record/Chart Review</u>	<u>Yes, Patient Report Only</u>	<u>No</u>	
d. Carotid arterial revascularization (endarterectomy or angioplasty)	M	P	N	RPC7D
e. Abdominal or thoracic aortic aneurysm repair	M	P	N	RPC7E
f. Renal arterial revascularization (bypass surgery or angioplasty)	M	P	N	RPC7F

Baseline/Randomization Visit Form: Patient Characteristics (RPCB Screen 5 of 14)

7. Has the patient ever received any of the following cardiovascular disease-related diagnoses, and/or undergone any of the following cardiovascular disease-related procedures? [If yes, indicate the documentation source-preferably Medical Record/Chart Review.]

	<u>Yes, Medical Record/Chart Review</u>	<u>Yes, Patient Report Only</u>	<u>No</u>	
g. Lower extremity arterial revascularization (bypass surgery or angioplasty)	M	P	N	RPC7G
h. Lower extremity amputation above the ankle	M	P	N	RPC7H

Baseline/Randomization Visit Form: Patient Characteristics (RPCB Screen 6 of 14)

<p>8. Has the patient ever been diagnosed with diabetes? RPC8</p> <p>M Yes, Documented in Medical Record</p> <p>P Yes, Documented by Patient Report Only</p> <p>N No</p> <p>D. Dietary Interview</p> <p>9. Over the last THREE MONTHS, have you eaten a one cup (8 oz.) serving of cold breakfast cereal at least three (3) times per week? RPC9</p> <p>Y Yes</p> <p>N No — Go to item 11</p>	<p>10. At least three (3) times per week, do you eat a one cup (8 oz.) serving of ANY of the following cold breakfast cereals?</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"></td> <td style="text-align: center;"><u>Yes</u></td> <td style="text-align: center;"><u>No</u></td> <td></td> </tr> <tr> <td colspan="4">Nabisco:</td> </tr> <tr> <td>a. 100% Bran</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">N</td> <td style="border: 1px solid red; padding: 2px;">RPC10A</td> </tr> <tr> <td colspan="4">General Mills:</td> </tr> <tr> <td>b. Multi Grain Cheerios Plus</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">N</td> <td style="border: 1px solid red; padding: 2px;">RPC10B</td> </tr> <tr> <td>c. Total Raisin Bran</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">N</td> <td style="border: 1px solid red; padding: 2px;">RPC10C</td> </tr> <tr> <td>d. Total Corn Flakes</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">N</td> <td style="border: 1px solid red; padding: 2px;">RPC10D</td> </tr> <tr> <td>e. Total Whole Grain</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">N</td> <td style="border: 1px solid red; padding: 2px;">RPC10E</td> </tr> </table>		<u>Yes</u>	<u>No</u>		Nabisco:				a. 100% Bran	Y	N	RPC10A	General Mills:				b. Multi Grain Cheerios Plus	Y	N	RPC10B	c. Total Raisin Bran	Y	N	RPC10C	d. Total Corn Flakes	Y	N	RPC10D	e. Total Whole Grain	Y	N	RPC10E
	<u>Yes</u>	<u>No</u>																															
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Baseline/Randomization Visit Form: Patient Characteristics (RPCB Screen 7 of 14)

<p>10. At least three (3) times per week, do you eat a one cup (8 oz.) serving of ANY of the following cold breakfast cereals?</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"></td> <td style="text-align: center;"><u>Yes</u></td> <td style="text-align: center;"><u>No</u></td> <td></td> </tr> <tr> <td colspan="4">Kellogg's:</td> </tr> <tr> <td>f. Smart Start</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">N</td> <td style="border: 1px solid red; padding: 2px;">RPC10F</td> </tr> <tr> <td>g. Product 19</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">N</td> <td style="border: 1px solid red; padding: 2px;">RPC10G</td> </tr> <tr> <td colspan="4">Quaker:</td> </tr> <tr> <td>h. Kretschmer Honey Crunch Wheat Germ</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">N</td> <td style="border: 1px solid red; padding: 2px;">RPC10H</td> </tr> </table>		<u>Yes</u>	<u>No</u>		Kellogg's:				f. Smart Start	Y	N	RPC10F	g. Product 19	Y	N	RPC10G	Quaker:				h. Kretschmer Honey Crunch Wheat Germ	Y	N	RPC10H	<p>11. Over the last THREE MONTHS, have you drunk a one cup (8 oz.) serving of ANY liquid or powdered dietary supplement at least three (3) times per week? RPC11</p> <p>Y Yes</p> <p>N No — Go to item 13</p>
	<u>Yes</u>	<u>No</u>																							
Kellogg's:																									
f. Smart Start	Y	N	RPC10F																						
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Quaker:																									
h. Kretschmer Honey Crunch Wheat Germ	Y	N	RPC10H																						

Baseline/Randomization Visit Form: Patient Characteristics (RPCB Screen 8 of 14)

<p>12. At least three (3) times per week, do you drink a one cup (8 oz.) serving of ANY of the following specific liquid or powdered dietary supplements?</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"></td> <td style="text-align: center;"><u>Yes</u></td> <td style="text-align: center;"><u>No</u></td> <td></td> </tr> <tr> <td>a. Ensure Plus HN</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">N</td> <td style="border: 1px solid red; padding: 2px;">RPC12A</td> </tr> <tr> <td>b. Replena</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">N</td> <td style="border: 1px solid red; padding: 2px;">RPC12B</td> </tr> <tr> <td>c. Sandoz Nutrition Citrotein</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">N</td> <td style="border: 1px solid red; padding: 2px;">RPC12C</td> </tr> <tr> <td>d. Pulmocare</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">N</td> <td style="border: 1px solid red; padding: 2px;">RPC12D</td> </tr> <tr> <td>e. Magnacal Renal</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">N</td> <td style="border: 1px solid red; padding: 2px;">RPC12E</td> </tr> <tr> <td>f. Any other?</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">N</td> <td style="border: 1px solid black; padding: 2px;">Go to item 13</td> </tr> <tr> <td>g. Specify other: _____</td> <td></td> <td></td> <td style="border: 1px solid red; padding: 2px;">RPC12F</td> </tr> <tr> <td></td> <td></td> <td></td> <td style="border: 1px solid red; padding: 2px;">RPC12G</td> </tr> </table>		<u>Yes</u>	<u>No</u>		a. Ensure Plus HN	Y	N	RPC12A	b. Replena	Y	N	RPC12B	c. Sandoz Nutrition Citrotein	Y	N	RPC12C	d. Pulmocare	Y	N	RPC12D	e. Magnacal Renal	Y	N	RPC12E	f. Any other?	Y	N	Go to item 13	g. Specify other: _____			RPC12F				RPC12G
	<u>Yes</u>	<u>No</u>																																		
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			RPC12G																																	

Baseline/Randomization Visit Form: Patient Characteristics (RPCB Screen 9 of 14)

E. Physical Activity Interview

Instructions: The following questions have to do with certain kinds of activities that you have done DURING THE PAST MONTH. These activities may have been done as part of your work, household tasks or during your leisure. [USE RESPONSE CARDS]

13. About how many times during the month did you participate in VIGOROUS activities that lasted at least 10 MINUTES and caused large increases in breathing, heart rate, or leg fatigue, or caused you to perspire?
[Show and read response card # 1]

RPC13

- A Not at all — Go to item 15
- B 1-3 Times per month
- C 1-2 Times per week
- D 3-4 Times per week
- E 5 or more times per week

Baseline/Randomization Visit Form: Patient Characteristics (RPCB Screen 10 of 14)

14. About how long did you do this vigorous activity(ies) each time?
[Show and read response card # 2]

- A 10-30 minutes
- B 31-60 minutes
- C More than 60 minutes

RPC14

15. Thinking about the walks you have taken during the past month. About how many times per month did you walk for at least 10 MINUTES or more without stopping which was NOT strenuous enough to cause large increases in breathing, heart rate, or leg fatigue, or cause you to perspire?
[Show and read response card # 3]

RPC15

- A Not at all — Go to item 17
- B 1-3 Times per month
- C 1-2 Times per week
- D 3-4 Times per week
- E 5 or more times per week

Baseline/Randomization Visit Form: Patient Characteristics (RPCB Screen 11 of 14)

16. When you did this walking, for how many minutes did you do it?
[Show and read response card # 4]

- A 10-30 minutes
- B 31-60 minutes
- C More than 60 minutes

RPC16

17. About how many hours a day do you spend moving around on your feet while doing things? Please report only the time that you are ACTUALLY MOVING.
[Show and read response card # 5]

RPC17

- A Not at all
- B Less than 1 hour per day
- C 1 to less than 3 hours per day
- D 3 to less than 5 hours per day
- E 5 to less than 7 hours per day
- F 7 or more hours per day

Baseline/Randomization Visit Form: Patient Characteristics (RPCB Screen 12 of 14)

18. Think about how much time you spend standing or moving around on your feet on an average day during the past month? About how many hours per day do you STAND? [Show and read response card # 6]

RPCB18

- A Not at all
- B Less than 1 hour per day
- C 1 to less than 3 hours per day
- D 3 to less than 5 hours per day
- E 5 to less than 7 hours per day
- F 7 or more hours per day

19. About how many hours did you spend sitting on an average day during the past month? [Show and read response card # 7]

RPC18

- A Not at all
- B Less than 3 hours
- C 3 to less than 6 hours
- D 6 to less than 8 hours
- E 8 or more hours

20. About how many flights of stairs do you climb UP each (1 flight equals 10 steps.)

of flights

RPC19

Baseline/Randomization Visit Form: Patient Characteristics (RPCB Screen 13 of 14)

F. Second Blood Pressure

21. Seated Blood Pressure #2:

a. Systolic:

RPC20A

b. Diastolic:

RPC20B

c. Indicate which arm: (prefer same arm as with first BP)

R Right

RPC20C

L Left

22. Average blood pressure:

See rand_derv_niddkv1 for average blood pressure

a. Average Systolic blood pressure: [Do not calculate. Automatically calculated by DMS program.]

RPC21A

b. Average Diastolic blood pressure: [Do not calculate. Automatically calculated by DMS program.]

RPC21B

Baseline/Randomization Visit Form: Patient Characteristics (RPCB Screen 14 of 14)

G. Administrative Information

23. Date of data collection:

/ /

Month Day Year

RPC22

25. Method of data collection:

RPCB25

- C Computer
- P Paper

24. Is this a screening/baseline combination visit?

Y Yes

RPCB24

N No

26. Initials of data collector:

Blind_staff_ID

REMINDERS:

Proceed to Baseline/Randomization/
Follow-Up Phlebotomy Collection Form

FAVORIT

RANDOMIZATION VISIT FORM: PATIENT CHARACTERISTICS

Folic Acid for Vascular Outcome
Reduction in Transplantation

FORM CODE: RPC VERSION: A 03/15/02

ID NUMBER:

CONTACT OCCASION:

SEQUENCE NUMBER:

PATIENT LAST NAME:

FIRST/MIDDLE INITIALS:

Randomization Visit Form: Patient Characteristics (RPCA Screen 1 of 14)

A. Clinic Examination

1. Seated Blood Pressure #1:

a. Systolic:

RPC1A

b. Diastolic:

RPC1B

c. Indicate which arm:
(right arm preferred)

R

Right

RPC1C

L

Left

2. Height (in inches = cm/2.54):

 in.

RPC2

3. Weight (in lbs. = kg/0.45):

 lbs.

RPC3

4. Body Mass Index: [Do not
calculate. Automatically
calculated by DMS program.]

RPC4

*See rand_derv_niddkv1
for BMI*

Randomization Visit Form: Patient Characteristics (RPCA Screen 2 of 14)

B. Smoking History

5a. Do you currently smoke or have you
ever smoked cigarettes? [Probe for
appropriate response]

RPC5A

A Never Smoked —

B Current Smoker (defined as
at least 1 cigarette per day)

C Ever Smoked —

b. How many years have you
smoked?

 years

RPC5B

5c. What is the average number of
cigarettes per day that you smoke
at the present time:

RPC5C

 cigarettes per day —

6. How long has it been since you
QUIT smoking? [Calculate using
most recent 'quit date']

a. years b. months

RPC6A

RPC6B

c. What was the average number of
cigarettes per day you smoked
when you were a smoker:

 cigarettes per day

RPC6C

d. How many years did you smoke?

 years

RPC6D

Randomization Visit Form: Patient Characteristics (RPCA Screen 3 of 14)

C. Medical History

7. Has the patient ever received any of the following cardiovascular disease-related diagnoses, and/or undergone any of the following cardiovascular disease-related procedures? [If yes, indicate the documentation source-preferably Medical Record/Chart Review.]

	<u>Yes, Medical Record/Chart Review</u>	<u>Yes, Patient Report Only</u>	<u>No</u>	
a. Myocardial infarction	M	P	N	RPC7A
b. Coronary artery revascularization (i.e., coronary artery bypass surgery or angioplasty)	M	P	N	RPC7B
c. Stroke (atherothrombotic or hemorrhagic)	M	P	N	RPC7C

Randomization Visit Form: Patient Characteristics (RPCA Screen 4 of 14)

7. Has the patient ever received any of the following cardiovascular disease-related diagnoses, and/or undergone any of the following cardiovascular disease-related procedures? [If yes, indicate the documentation source-preferably Medical Record/Chart Review.]

	<u>Yes, Medical Record/Chart Review</u>	<u>Yes, Patient Report Only</u>	<u>No</u>	
d. Carotid arterial revascularization (endarterectomy or angioplasty)	M	P	N	RPC7D
e. Abdominal or thoracic aortic aneurysm repair	M	P	N	RPC7E
f. Renal arterial revascularization (bypass surgery or angioplasty)	M	P	N	RPC7F

Randomization Visit Form: Patient Characteristics (RPCA Screen 5 of 14)

7. Has the patient ever received any of the following cardiovascular disease-related diagnoses, and/or undergone any of the following cardiovascular disease-related procedures? [If yes, indicate the documentation source-preferably Medical Record/Chart Review.]

	<u>Yes, Medical Record/Chart Review</u>	<u>Yes, Patient Report Only</u>	<u>No</u>	
g. Lower extremity arterial revascularization (bypass surgery or angioplasty)	M	P	N	RPC7G
h. Lower extremity amputation above the ankle	M	P	N	RPC7H

Randomization Visit Form: Patient Characteristics (RPCA Screen 6 of 14)

8. Has the patient ever been diagnosed with diabetes?	RPC8	10. At least three (3) times per week, do you eat a one cup (8 oz.) serving of ANY of the following cold breakfast cereals?	<u>Yes</u>	<u>No</u>	
M Yes, Documented in Medical Record					
P Yes, Documented by Patient Report Only					
N No					
D. Dietary Interview		Nabisco:			
9. Over the last THREE MONTHS, have you eaten a one cup (8 oz.) serving of cold breakfast cereal at least three (3) times per week?	RPC9	a. 100% Bran	Y	N	RPC10A
		General Mills:			
Y Yes		b. Multi Grain Cheerios Plus	Y	N	RPC10B
N No		c. Total Raisin Bran	Y	N	RPC10C
Go to item 11		d. Total Corn Flakes	Y	N	RPC10D
		e. Total Whole Grain	Y	N	RPC10E

Randomization Visit Form: Patient Characteristics (RPCA Screen 7 of 14)

10. At least three (3) times per week, do you eat a one cup (8 oz.) serving of ANY of the following cold breakfast cereals?	<u>Yes</u>	<u>No</u>	RPC11
Kellogg's:			
f. Smart Start	Y	N	RPC10F
g. Product 19	Y	N	RPC10G
Quaker:			RPC10H
h. Kretschmer Honey Crunch Wheat Germ	Y	N	
11. Over the last THREE MONTHS, have you drunk a one cup (8 oz.) serving of ANY liquid or powdered dietary supplement at least three (3) times per week?	Y	Yes	
	N	No	Go to item 13

Randomization Visit Form: Patient Characteristics (RPCA Screen 8 of 14)

12. At least three (3) times per week, do you drink a one cup (8 oz.) serving of ANY of the following specific liquid or powdered dietary supplements?	<u>Yes</u>	<u>No</u>	
a. Ensure Plus HN	Y	N	RPC12A
b. Replena	Y	N	RPC12B
c. Sandoz Nutrition Citrotein	Y	N	RPC12C
d. Pulmocare	Y	N	RPC12D
e. Magnacal Renal	Y	N	RPC12E
f. Any other?	Y	N	Go to item 13 RPC12F
g. Specify other: _____			RPC12G

Randomization Visit Form: Patient Characteristics (RPCA Screen 9 of 14)

E. Physical Activity Interview

Instructions: The following questions have to do with certain kinds of activities that you have done DURING THE PAST MONTH. These activities may have been done as part of your work, household tasks or during your leisure. [USE RESPONSE CARDS]

13. About how many times during the past month did you participate in VIGOROUS activities that lasted at least 10 MINUTES and caused large increases in breathing and heart rate, or leg fatigue, or caused you to perspire?
[Show and read response card # 1]

RPC13

- A Not at all —
- B 1-3 Times per month
- C 1-2 Times per week
- D 3-4 Times per week
- E 5 or more times per week

Randomization Visit Form: Patient Characteristics (RPCA Screen 10 of 14)

14. About how long on the average did you do this (these) vigorous activities each time?
[Show and read response card # 2]

RPC14

- A 10-30 minutes
- B 31-60 minutes
- C More than 60 minutes

15. Thinking about the walks you have taken during the past month, about how many times did you walk for at least 10 MINUTES or more without stopping and which was NOT strenuous enough to cause large increases in your breathing and heart rate, or result in leg fatigue, or cause you to perspire?
[Show and read response card # 3]

RPC15

- A Not at all —
- B 1-3 Times per month
- C 1-2 Times per week
- D 3-4 Times per week
- E 5 or more times per week

Randomization Visit Form: Patient Characteristics (RPCA Screen 11 of 14)

16. When you did this walking, for how many minutes on the average did you do it each time?
[Show and read response card # 4]

RPC16

- A 10-30 minutes
- B 31-60 minutes
- C More than 60 minutes

17. About how many hours per day do you spend moving about on your feet doing things on a typical day during the past month? Please report on the time that you were ACTUALLY MOVING.
[Show and read response card # 5]

RPC17

- A Not at all
- B Less than 1 hour per day
- C 1 to less than 3 hours per day
- D 3 to less than 5 hours per day
- E 5 to less than 7 hours per day
- F 7 or more hours per day

Randomization Visit Form: Patient Characteristics (RPCA Screen 12 of 14)

18. About how many hours did you spend sitting on an average day during the past month?
[Show and read response card # 6]

RPC18

- A Not at all
- B Less than 3 hours
- C 3 to less than 6 hours
- D 6 to less than 8 hours
- E 8 or more hours

19. About how many flights of stairs do you climb UP each day on a typical day during the past month? (1 flight equals 10 steps.)

RPC19

of flights

Randomization Visit Form: Patient Characteristics (RPCA Screen 13 of 14)

F. Second Blood Pressure

20. Seated Blood Pressure #2:

21. Average blood pressure:

See rand_deriv_niddkv1 for average blood pressure

a. Systolic:

RPC20A

b. Diastolic:

RPC20B

c. Indicate which arm:
(prefer same arm as with first BP)

R Right

RPC20C

L Left

a. Average Systolic blood pressure: [Do not calculate. Automatically calculated by DMS program.]

RPC21A

b. Average Diastolic blood pressure: [Do not calculate. Automatically calculated by DMS program.]

RPC21B

Randomization Visit Form: Patient Characteristics (RPCA Screen 14 of 14)

G. Administrative Information

REMINDERS:

22. Date of data collection:

RPC22

 / /

Month Day Year

Proceed to Randomization/Follow-Up Phlebotomy Collection Form

Schedule 6-month phone follow-up

Schedule 12-month clinic visit

23. Initials of data collector:

Blind_staff_ID