

FAVORIT

FOLLOW-UP CONTACT FORM

Folic Acid for Vascular Outcome
Reduction in Transplantation

FORM CODE: FUP VERSION: C 11/01/2007

ID NUMBER:

CONTACT OCCASION:

SEQUENCE NUMBER:

PATIENT LAST NAME:

FIRST/MIDDLE INITIALS:

FOLLOW-UP CONTACT FORM (FUPC Screen 1 of 24)

A. Contact Information

1. Type of Contact:

FUP1

A Regularly Scheduled Clinic Visit —

B Regularly Scheduled Brief/Phone Contact —

C Brief/Phone Contact Replacing Clinic Visit —

D Clinic Visit Replacing Brief/Phone Contact —

E Missed Contact

FOLLOW-UP CONTACT FORM (FUPC Screen 2 of 24)

2. Indicate the main reason the visit was missed:

FUP2

A Participant refused —

B Participant incapacitated —

C Participant withdrew consent

D Participant location unknown —

E Oversight —

F Participant died —

3a. Date participant withdrew consent: / /
Month Day Year

FUP3A

b. Did the participant give reason for withdrawing consent?

FUP3B

Y Yes

N No

Specify reason for withdrawal _____

FOLLOW-UP CONTACT FORM (FUPC Screen 3 of 24)

4. Is participant currently on study medication?	FUP4	5c. Indicate which arm: (right arm preferred)	R Right
Y Yes		FUP5C	L Left
N No		6. Height (in inches = cm/2.54):	FUP6
U Unknown		<input type="text"/> <input type="text"/> <input type="text"/> in.	
<input type="text" value="Go to Item 39"/>		7. Weight (in pounds = kg/0.45):	FUP7
B. Clinic Examination		<input type="text"/> <input type="text"/> <input type="text"/> lbs.	
5. Seated Blood Pressure #1:		8. Body Mass Index: [Do not calculate. Automatically calculated by DMS program.]	Variable found in rand_deriv_niddkv1
a. Systolic: <input type="text"/> <input type="text"/> <input type="text"/>	FUP5A	<input type="text"/> <input type="text"/>	
b. Diastolic: <input type="text"/> <input type="text"/> <input type="text"/>	FUP5B		

FOLLOW-UP CONTACT FORM (FUPC Screen 4 of 24)

C. Follow-Up Interview		
9. Since our last contact on <mm/dd/yyyy>, have you been hospitalized overnight for any reason?		FUP9
Y Yes	— <input type="text" value="If 'Yes', following completion of this form, complete one Hospitalization Form for EACH overnight hospitalization that has occurred since the last contact."/>	
N No		
10. Have you undergone angioplasty of the lower extremity arteries, renal arteries, or coronary arteries, as an outpatient?		FUP10
Y Yes	— <input type="text" value="If 'Yes', following completion of this form, complete one Hospitalization Form for EACH outpatient angioplasty that has occurred since the last contact."/>	
N No		

FOLLOW-UP CONTACT FORM (FUPC Screen 5 of 24)

The next set of items deal with bone fractures that you have had since the last contact.

11a. Have you had any bone fractures since our last contact on <mm/dd/yyyy>? **FUPC11A**

Y Yes

N No —

11b. How many bone fractures have you had since last contact? **FUPC11B**

FOLLOW-UP CONTACT FORM (FUPC Screen 6 of 24)

Location of Bone Fractures:

1-toe 2-foot 3-ankle 4-leg (fibula, tibia, knee, femur) 5-hand 6-arm (ulna, radius, humerus) 7-wrist 8-hip 9-pelvis 10-ribs 11-sternum 12-clavicle 13-cranium 14-other

11c1. In which part of the body did you have the bone fracture? **FUPC11C1**

Location of Bone Fracture #1:

(If other specify in notelog)

11d1. What was the date of the fracture? **FUPC11D1**

/ /

Month Day Year

11e1. How did the bone fracture occur? **FUPC11E1**

F Fall

C Collision or accident

S Stress fracture

O Other

(If other specify in notelog)

11f1. Where was this fracture treated? **FUPC11F1**

I Hospital —

O Other _____

(If other specify in notelog)

FOLLOW-UP CONTACT FORM (FUPC Screen 7 of 24)

Location of Bone Fractures:

1-toe 2-foot 3-ankle 4-leg (fibula, tibia, knee, femur) 5-hand 6-arm (ulna, radius, humerus) 7-wrist 8-hip 9-pelvis 10-ribs 11-sternum 12-clavicle 13-cranium 14-other

11c2. In which part of the body did you have the bone fracture? **FUPC11C2**

Location of Bone Fracture #2:

(If other specify in notelog)

11d2. What was the date of the fracture? **FUPC11D2**

/ /

Month Day Year

11e2. How did the bone fracture occur? **FUPC11E2**

F Fall

C Collision or accident

S Stress fracture

O Other

(If other specify in notelog)

11f2. Where was this fracture treated? **FUPC11F2**

I Hospital —

O Other _____

(If other specify in notelog)

FOLLOW-UP CONTACT FORM (FUPC Screen 8 of 24)

Location of Bone Fractures:

1-toe 2-foot 3-ankle 4-leg (fibula, tibia, knee, femur) 5-hand 6-arm (ulna, radius, humerus) 7-wrist 8-hip 9-pelvis 10-ribs 11-sternum 12-clavicle 13-cranium 14-other

11c3. In which part of the body did you have the bone fracture? **FUPC11C3**

Location of Bone Fracture #3:

(If other specify in notelog)

11d3. What was the date of the fracture? **FUPC11D3**

/ /
Month Day Year

11e3. How did the bone fracture occur? **FUPC11E3**

- F Fall
- C Collision or accident
- S Stress fracture
- O Other

(If other specify in notelog)

11f3. Where was this fracture treated? **FUPC11F3**

I Hospital — Complete a HOS form

O Other _____

(If other specify in notelog)

FOLLOW-UP CONTACT FORM (FUPC Screen 9 of 24)

12a. Have you been told by your physician that your renal graft function has deteriorated? **FUP11A**

Y Yes

N No — Go to item 13

12b. Were you hospitalized for this? **FUP11B**

Y Yes — If not captured in items 9 or 10, following completion of this form complete a Hospitalization Form.

N No

12c. Are you currently on dialysis? **FUPA12A**

Y Yes — If Yes, following completion of this form complete an Initiation of Dialysis Fax Notification Form.

N No — Go to Item 13

12d. Date dialysis was initiated: **FUP12B**

/ /
Month Day Year

FOLLOW-UP CONTACT FORM (FUPC Screen 10 of 24)

D. Side effects monitoring:		<u>Yes</u>	<u>No</u>
13. Have you experienced any side effects that may be associated with the study vitamin?	FUP13		
Y Yes		Y	N FUP14C
N No	Go to Item 15		
14 Do not probe specific symptoms, but record Yes or No to items 14a - f based on the patient's response:			
	<u>Yes</u>	<u>No</u>	
a. Itching	Y	N FUP14A	
b. Gastrointestinal disturbances	Y	N FUP14B	
14c. Headache	Y	N FUP14D	
d. Fatigue	Y	N FUP14E	
e. Change in appetite or weight	Y	N FUP14E	
f. Other significant side effect	Y	N FUP14F	Go to Item 15
Specify other significant side effect _____			FUP14F

FOLLOW-UP CONTACT FORM (FUPC Screen 11 of 24)

E. Study Medication Interview

15. Over the past six months, have you been taking the study vitamin every day, almost every day, or less frequently? **FUP15**

A Takes vitamin every day — Go to Item 18

B Takes vitamin almost every day — Go to Item 18

C Takes vitamin approximately 75% to 90% of the time — Go to Item 17

D Takes vitamin approximately 50% to 74% of the time — Go to Item 17

E Takes vitamin approximately 25% to 49% of the time — Go to Item 17

F Seldom takes vitamin (takes vitamin occasionally, but less than 25% of the time) — Go to Item 17

G Does not take study vitamin

FOLLOW-UP CONTACT FORM (FUPC Screen 12 of 24)

16. [If patient does not take study vitamin, can patient be converted to resume taking the study vitamin?] **FUP16**

S Successfully converted patient to resume study vitamin

U Unsuccessful attempt to convert patient to resume study vitamin

17. What is the primary reason that you did not take the study vitamin every day (or almost every day)? **FUP17**

A Patient forgets

B Medication was misplaced

C Patient experiences side effects

D Other reason: _____

FOLLOW-UP CONTACT FORM (FUPC Screen 13 of 24)

18. Did you take the study vitamin today? FUP18

Y Yes

N No

19. Other than the assigned study vitamin tablets, are you currently using any vitamin supplements (multivitamin, B-group vitamins, or individual vitamins) containing folic acid ("folate"), vitamin B6, or vitamin B12? FUP22

Y Yes

N No — Go to Item 21

20. Are you taking:

	<u>Yes</u>	<u>No</u>	
a. Folic Acid	Y	N	FUP23A
b. Vitamin B6	Y	N	FUP23B
c. Vitamin B12	Y	N	FUP23C

21. [Is this a Brief/Phone Contact?] FUP24

Y Yes — Go to Item 39

N No

FOLLOW-UP CONTACT FORM (FUPC Screen 14 of 24)

F. Risk Factor And Interview Information FUP25

Blood Pressure:

22. Is the patient currently undergoing treatment for hypertension with one or more specific anti-hypertensive medications?

Y Yes

N No

Smoking History:

23a. Do you currently smoke or have you ever smoked cigarettes? FUP26A
[Probe for appropriate response]

A Never Smoked — Go to Item 25

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

C Ever Smoked — Go to Item 24

23b. How many years have you smoked? FUP26B

 years

FOLLOW-UP CONTACT FORM (FUPC Screen 15 of 24)

c. What is the average number of cigarettes per day that you smoke at the present time? FUP26C

 cigarettes per day — Go to Item 25

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

a. years FUP27A b. months FUP27B

c. What was the average number of cigarettes per day you smoked when you were a smoker? FUP27C

 cigarettes per day

24d. How many years did you smoke? FUP27D

 years

Dietary Interview:

25. 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? FUP28

Y Yes

N No — Go to Item 27

FOLLOW-UP CONTACT FORM (FUPC Screen 16 of 24)

		<u>Yes</u>	<u>No</u>	
26. At least three (3) times per week, do you eat a one cup (8 oz.) serving of ANY of the following cold breakfast cereals?				
				Kellogg's
				f. Smart Start
		Y	N	FUP29F
				Nabisco
		<u>Yes</u>	<u>No</u>	
	a. 100% Bran	Y	N	FUP29A
				Kellogg's
				g. Product 19
		Y	N	FUP29G
				General Mills
	b. Multi Grain Cheerios Plus	Y	N	FUP29B
				Quaker
				h. Kretschmer Honey Crunch Wheat Germ
		Y	N	FUP29H
	c. Total Raisin Bran	Y	N	FUP29C
	d. Total Corn Flakes	Y	N	FUP29D
	e. Total Whole Grain	Y	N	FUP29E

FOLLOW-UP CONTACT FORM (FUPC Screen 17 of 24)

Drink Supplements:

27. Over the past 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? **FUP30**

Y Yes

N No

FOLLOW-UP CONTACT FORM (FUPC Screen 18 of 24)

28. 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? **[Read Each Choice]**

		<u>Yes</u>	<u>No</u>	
a.	Ensure Plus HN:	Y	N	FUP31A
b.	Replena:	Y	N	FUP31B
c.	Sandoz Nutrition Citrotein:	Y	N	FUP31C
d.	Pulmocare:	Y	N	FUP31D
e.	Magnacal Renal:	Y	N	FUP31E
f.	Any other?	Y	N	<input type="button" value="Go to Item 29"/> FUP31F
g.	Specify other: _____			

FOLLOW-UP CONTACT FORM (FUPC Screen 19 of 24)

G. Physical Activity

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]

29. 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]

FUP32

- 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

FOLLOW-UP CONTACT FORM (FUPC Screen 20 of 24)

30. About how long did you do this vigorous activities each time?
[Show and read response card # 2]

FUP33

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

31. Think 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]

FUP34

- 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

FOLLOW-UP CONTACT FORM (FUPC Screen 21 of 24)

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

FUP35

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

33. 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]

FUP36

- 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

FOLLOW-UP CONTACT FORM (FUPC Screen 22 of 24)

34. 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]
- 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

FUPB34

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

FUP37

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

FUP38

of flights

FOLLOW-UP CONTACT FORM (FUPC Screen 23 of 24)

H. SECOND BLOOD PRESSURE

37. Seated Blood Pressure #2:

a. Systolic:

FUP39A

b. Diastolic:

FUP39B

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

R Right

FUP39C

L Left

38. Average Blood Pressure:

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

BP variables found in rand_deriv_niddkv1

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

FOLLOW-UP CONTACT FORM (FUPC Screen 24 of 24)

39. Date of Data Collection:

/ /
Month Day Year

FUP41

If any hospitalizations or outpatient angioplasties were reported, complete Hospitalization Form.

If the patient is deceased, complete an Outcomes Documentation Form.

40. Method of data collection:

C Computer

P Paper

FUPB40

If the patient missed contact and is incapacitated, location is unknown or died, complete Informant Interview Form.

If this is a clinic visit, complete Medication Survey Form and Phlebotomy Form.

41. Examiner's Initials:

Blind_staff_ID

Schedule/Remind participant of next study contact.

FAVORIT

FOLLOW-UP CONTACT FORM

Folic Acid for Vascular Outcome
Reduction in Transplantation

FORM CODE: FUP VERSION: B 02/21/05

ID NUMBER:

CONTACT OCCASION:

SEQUENCE NUMBER:

PATIENT LAST NAME:

FIRST/MIDDLE INITIALS:

FOLLOW-UP CONTACT FORM (FUPB Screen 1 of 20)

A. Contact Information

1. Type of Contact:

A Regularly Scheduled Clinic Visit —

FUP1

B Regularly Scheduled Brief/Phone Contact —

C Brief/Phone Contact Replacing Clinic Visit —

D Clinic Visit Replacing Brief/Phone Contact —

E Missed Contact

FOLLOW-UP CONTACT FORM (FUPB Screen 2 of 20)

2. Indicate the main reason the visit was missed:

A Participant refused —

FUP2

B Participant incapacitated —

C Participant withdrew consent

D Participant location unknown —

E Oversight —

F Participant died —

3a. Date participant withdrew consent: / /
Month Day Year

FUP3A

b. Did the participant give reason for withdrawing consent?

Y Yes

N No

Specify reason for withdrawal _____

FUP3B

FOLLOW-UP CONTACT FORM (FUPB Screen 6 of 20)

D. Side effects monitoring:		<u>Yes</u>	<u>No</u>
13. Have you experienced any side effects that may be associated with the study vitamin?	FUP13	Y	N
Y Yes			
N No	Go to Item 15		
14 Do not probe specific symptoms, but record Yes or No to items 14a - f based on the patient's response:			
		<u>Yes</u>	<u>No</u>
a. Itching	FUP14A	Y	N
b. Gastrointestinal disturbances	FUP14B	Y	N
14c. Headache		Y	N
d. Fatigue		Y	N
e. Change in appetite or weight		Y	N
f. Other significant side effect		Y	N
Specify other significant side effect _____			

FOLLOW-UP CONTACT FORM (FUPB Screen 7 of 20)

E. Study Medication Interview

15. Over the past six months, have you been taking the study vitamin every day, almost every day, or less frequently? **FUP15**

A Takes vitamin every day — Go to Item 18

B Takes vitamin almost every day — Go to Item 18

C Takes vitamin approximately 75% to 90% of the time — Go to Item 17

D Takes vitamin approximately 50% to 74% of the time — Go to Item 17

E Takes vitamin approximately 25% to 49% of the time — Go to Item 17

F Seldom takes vitamin (takes vitamin occasionally, but less than 25% of the time) — Go to Item 17

G Does not take study vitamin

FOLLOW-UP CONTACT FORM (FUPB Screen 8 of 20)

16. [If patient does not take study vitamin, can patient be converted to resume taking the study vitamin?] **FUP16**

S Successfully converted patient to resume study vitamin

U Unsuccessful attempt to convert patient to resume study vitamin

17. What is the primary reason that you did not take the study vitamin every day (or almost every day)? **FUP17**

A Patient forgets

B Medication was misplaced

C Patient experiences side effects

D Other reason: _____

FOLLOW-UP CONTACT FORM (FUPB Screen 9 of 20)

18. Did you take the study vitamin today? FUP18

Y Yes

N No

19. Other than the assigned study vitamin tablets, are you currently using any vitamin supplements (multivitamin, B-group vitamins, or individual vitamins) containing folic acid ("folate"), vitamin B6, or vitamin B12? FUP22

Y Yes

N No — Go to Item 21

20. Are you taking:

	<u>Yes</u>	<u>No</u>	
a. Folic Acid	Y	N	FUP23A
b. Vitamin B6	Y	N	FUP23B
c. Vitamin B12	Y	N	FUP23C

21. [Is this a Brief/Phone Contact?] FUP24

Y Yes — Go to Item 39

N No

FOLLOW-UP CONTACT FORM (FUPB Screen 10 of 20)

F. Risk Factor And Interview Information FUP25

Blood Pressure:

22. Is the patient currently undergoing treatment for hypertension with one or more specific anti-hypertensive medications?

Y Yes

N No

Smoking History:

23a. Do you currently smoke or have you ever smoked cigarettes? FUP26A
[Probe for appropriate response]

A Never Smoked — Go to Item 25

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

C Ever Smoked — Go to Item 24

23b. How many years have you smoked? FUP26B

years

FOLLOW-UP CONTACT FORM (FUPB Screen 11 of 20)

c. What is the average number of cigarettes per day that you smoke at the present time: FUP26C

cigarettes per day — Go to Item 25

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

a. years FUP27A b. months FUP27B

c. What was the average number of cigarettes per day you smoked when you were a smoker: FUP27C

cigarettes per day

24d. How many years did you smoke? FUP27D

years

Dietary Interview:

25. 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? FUP28

Y Yes

N No — Go to Item 27

FOLLOW-UP CONTACT FORM (FUPB Screen 12 of 20)

		<u>Yes</u>	<u>No</u>		<u>Yes</u>	<u>No</u>
26. At least three (3) times per week, do you eat a one cup (8 oz.) serving of ANY of the following cold breakfast cereals?						
				Kellogg's		
				f. Smart Start	Y	N
						FUP29F
				Nabisco		
		<u>Yes</u>	<u>No</u>			
a.	100% Bran	Y	N	g. Product 19	Y	N
						FUP29G
				General Mills		
b.	Multi Grain Cheerios Plus	Y	N	h. Kretschmer Honey Crunch Wheat Germ	Y	N
						FUP29H
c.	Total Raisin Bran	Y	N			
						FUP29C
d.	Total Corn Flakes	Y	N			
						FUP29D
e.	Total Whole Grain	Y	N			
						FUP29E

FOLLOW-UP CONTACT FORM (FUPB Screen 13 of 20)

Drink Supplements:

27. Over the past 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 —

FUP30

FOLLOW-UP CONTACT FORM (FUPB Screen 14 of 20)

28. 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? **[Read Each Choice]**

		<u>Yes</u>	<u>No</u>	
a.	Ensure Plus HN:	Y	N	FUP31A
b.	Replena:	Y	N	FUP31B
c.	Sandoz Nutrition Citrotein:	Y	N	FUP31C
d.	Pulmocare:	Y	N	FUP31D
e.	Magnacal Renal:	Y	N	FUP31E
f.	Any other?	Y	N	<input type="text" value="Go to Item 29"/> FUP31F
g.	Specify other: _____			

FOLLOW-UP CONTACT FORM (FUPB Screen 15 of 20)

G. Physical Activity

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]

29. 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]

FUP32

- 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

FOLLOW-UP CONTACT FORM (FUPB Screen 16 of 20)

30. About how long did you do this vigorous activities each time?
[Show and read response card # 2]

FUP33

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

31. Think 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]

FUP34

- 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

FOLLOW-UP CONTACT FORM (FUPB Screen 17 of 20)

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

FUP35

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

33. 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]

FUP36

- 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

FOLLOW-UP CONTACT FORM (FUPB Screen 18 of 20)

34. 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]
- 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

FUPB34

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

FUP37

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

FUP38

of flights

FOLLOW-UP CONTACT FORM (FUPB Screen 19 of 20)

H. SECOND BLOOD PRESSURE

37. Seated Blood Pressure #2:

a. Systolic:

FUP39A

b. Diastolic:

FUP39B

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

FUP39C

L Left

38. Average Blood Pressure:

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

BP variables found in rand_derv_niddkv1

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

FOLLOW-UP CONTACT FORM (FUPB Screen 20 of 20)

39. Date of Data Collection:

/ /
Month Day Year

FUP41

If any hospitalizations or outpatient angioplasties were reported, complete Hospitalization Form.

If the patient is deceased, complete an Outcomes Documentation Form.

40. Method of data collection:

- C Computer
- P Paper

FUPB40

If the patient missed contact and is incapacitated, location is unknown or died, complete Informant Interview Form.

If this is a clinic visit, complete Medication Survey Form and Phlebotomy Form.

41. Examiner's Initials:

Blind_staff_ID

Schedule/Remind participant of next study contact.

FAVORIT

FOLLOW-UP CONTACT FORM

Folic Acid for Vascular Outcome
Reduction in Transplantation

FORM CODE: FUP

VERSION: A

03/25/02

ID NUMBER:

CONTACT OCCASION:

SEQUENCE NUMBER:

PATIENT LAST NAME:

FIRST/MIDDLE INITIALS:

This form should be completed for all Semi-Annual and Annual follow-up visits.

Contact #:	2	3	4	5	6	7	8	9	10	11
Study Month:	6	12	18	24	30	36	42	48	54	60

FOLLOW-UP CONTACT FORM (FUPA Screen 1 of 21)

A. Contact Information

FUP1

1. Type of Contact:

A Regularly Scheduled Clinic Visit —

B Regularly Scheduled Telephone Contact —

C Phone Contact Replacing Clinic Visit —

D Clinic Visit Replacing Phone Contact —

E Missed Contact

FOLLOW-UP CONTACT FORM (FUPA Screen 2 of 21)

2. Indicate the main reason the visit was missed:

A Participant refused —

FUP2

B Participant incapacitated —

C Participant withdrew consent

D Participant location unknown —

E Oversight —

F Participant died —

3a. Date participant withdrew consent: / /
Month Day Year

FUP3A

b. Did the participant give reason for withdrawing consent?

Y Yes
N No

FUP3B

Specify reason for withdrawal _____

FOLLOW-UP CONTACT FORM (FUPA Screen 3 of 21)

4. Is participant currently on study medication?

Y Yes
N No
U Unknown

5c. Indicate which arm: (right arm preferred) Right
 Left

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

7. Weight (in pounds = kg/0.45): lbs.

B. Clinic Examination

5. Seated Blood Pressure #1:

a. Systolic:

b. Diastolic:

8. Body Mass Index: [Do not calculate. Automatically calculated by DMS program.]
Variable found in rand_derv_niddkv1

FOLLOW-UP CONTACT FORM (FUPA Screen 4 of 21)

C. Follow-Up Interview

9. Since our last contact on <mm/dd/yyyy>, have you been hospitalized overnight for any reason? **FUP9**

- Y Yes
- N No

If "Yes", following completion of this form, complete one Hospitalization Form for EACH overnight hospitalization that has occurred since the last contact.

10. Have you undergone angioplasty of the lower extremity arteries, renal arteries, or coronary arteries, as an outpatient? **FUP10**

- Y Yes
- N No

If "Yes", following completion of this form, complete one Hospitalization Form for EACH outpatient angioplasty that has occurred since the last contact.

11a. Have you been told by your physician that your renal graft function has deteriorated? **FUP11A**

- Y Yes
- N No

Go to item 13

FOLLOW-UP CONTACT FORM (FUPA Screen 5 of 21)

11b. Were you hospitalized for this? **FUP11B**

- Y Yes
- N No

If not captured above, following completion of this form complete a Hospitalization Form.

12a. Have you re-initiated dialysis? **FUPA12A**

- Y Yes
- N No

Go to Item 13

b. Date dialysis was re-initiated:

		/			/				
--	--	---	--	--	---	--	--	--	--

Month Day Year

FUP12B

FOLLOW-UP CONTACT FORM (FUPA Screen 6 of 21)

D. Side effects monitoring:

		<u>Yes</u>	<u>No</u>
13. Have you experienced any side effects that may be associated with the study vitamin?	FUP13		
Y Yes		Y	N FUP14C
N No	Go to Item 15		
			d. Fatigue Y N FUP14D
			e. Change in appetite or weight Y N FUP14E
14 Do not probe specific symptoms, but record Yes or No to items 14a - f based on the patient's response:			f. Other significant side effect Y N Go to Item 15
	<u>Yes</u>	<u>No</u>	
a. Itching	Y	N	FUP14A
b. Gastrointestinal disturbances	Y	N	FUP14B
			Specify other significant side effect _____ FUP14F

FOLLOW-UP CONTACT FORM (FUPA Screen 7 of 21)

E. Study Medication Interview

15. Over the past six months, have you been taking the study vitamin every day, almost every day, or less frequently? **FUP15**

A Takes vitamin every day — Go to Item 18

B Takes vitamin almost every day — Go to Item 18

C Takes vitamin approximately 75% to 90% of the time — Go to Item 17

D Takes vitamin approximately 50% to 74% of the time — Go to Item 17

E Takes vitamin approximately 25% to 49% of the time — Go to Item 17

F Seldom takes vitamin (takes vitamin occasionally, but less than 25% of the time) — Go to Item 17

G Does not take study vitamin

FOLLOW-UP CONTACT FORM (FUPA Screen 8 of 21)

16. [If patient does not take study vitamin, can patient be converted to resume taking the study vitamin?]

FUP16

S Successfully converted patient to resume study vitamin

U Unsuccessful attempt to convert patient to resume study vitamin

17. What is the primary reason that you did not take the study vitamin every day (or almost every day)?

FUP17

A Patient forgets

B Medication was misplaced

C Patient experiences side effects

D Other reason: _____

FOLLOW-UP CONTACT FORM (FUPA Screen 9 of 21)

18. Did you take the study vitamin today?

FUP18

Y Yes

N No

19. [Total number of bottles dispensed to the participant since the last pill count:]

FUP19

--	--

20. [Total number of bottles the participant brought to the clinic:]

FUPA20

--	--

21. [Obtain and record pill count:]

FUPA21

--	--	--

*FUP19-FUPA21A
Moved to VDL
2/21/05. Use
adher dataset for
these variables.*

FOLLOW-UP CONTACT FORM (FUPA Screen 10 of 21)

22. Other than the assigned study vitamin tablets, are you currently using any vitamin supplements (multivitamin, B-group vitamins, or individual vitamins) containing folic acid ("folate"), vitamin B6, or vitamin B12?

FUP22

Y Yes

N No — Go to Item 24

23. Are you taking:

Yes No

a. Folic Acid

Y

N

FUP23A

b. Vitamin B6

Y

N

FUP23B

c. Vitamin B12

Y

N

FUP23C

24. [Is this a Telephone Contact?]

FUP24

Y Yes — Go to Item 41

N No

FOLLOW-UP CONTACT FORM (FUPA Screen 11 of 21)

F. Risk Factor And Interview Information

FUP25

Blood Pressure:

25. Is the patient currently undergoing treatment for hypertension with one or more specific anti-hypertensive medications?

Y Yes

N No

Smoking History:

26a. Do you currently smoke or have you ever smoked cigarettes? [Probe for appropriate response]

FUP26A

A Never Smoked — Go to Item 28

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

C Ever Smoked — Go to Item 27

26b. How many years have you smoked?

years

FUP26B

FOLLOW-UP CONTACT FORM (FUPA Screen 12 of 21)

c. What is the average number of cigarettes per day that you smoke at the present time: FUP26C

cigarettes per day — Go to Item 28

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

a. years FUP27A b. months FUP27B

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

cigarettes per day FUP27C

27d. How many years did you smoke? FUP27D

years

Dietary Interview:

28. 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? FUP28

Y Yes

N No — Go to Item 30

FOLLOW-UP CONTACT FORM (FUPA Screen 13 of 21)

29. 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>		<u>Yes</u>	<u>No</u>
Nabisco					
a. 100% Bran	Y	N	FUP29A		
General Mills					
b. Multi Grain Cheerios Plus	Y	N	FUP29B		
c. Total Raisin Bran	Y	N	FUP29C		
d. Total Corn Flakes	Y	N	FUP29D		
e. Total Whole Grain	Y	N	FUP29E		
			Kellogg's		
			f. Smart Start	Y	N
			g. Product 19	Y	N
			Quaker		
			h. Kretschmer Honey Crunch Wheat Germ	Y	N

FUP29F

FUP29G

FUP29H

FOLLOW-UP CONTACT FORM (FUPA Screen 14 of 21)

Drink Supplements:

30. Over the past 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? FUP30

Y Yes

N No — Go to Item 32

FOLLOW-UP CONTACT FORM (FUPA Screen 15 of 21)

31. 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? [Read Each Choice]

	<u>Yes</u>	<u>No</u>	
a. Ensure Plus HN:	Y	N	FUP31A
b. Replena:	Y	N	FUP31B
c. Sandoz Nutrition Citrotein:	Y	N	FUP31C
d. Pulmocare:	Y	N	FUP31D
e. Magnacal Renal:	Y	N	FUP31E
f. Any other?	Y	N	Go to Item 32 FUP31F
g. Specify other: _____			

FOLLOW-UP CONTACT FORM (FUPA Screen 16 of 21)

G. Physical Activity

FUP32

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]

32. 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 your breathing and heart rate, or leg fatigue, or caused you to perspire?
[Show and read response card # 1]

- A Not at all — Go to Item 34
- 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

FOLLOW-UP CONTACT FORM (FUPA Screen 17 of 21)

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

FUP33

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

34. Think 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 breathing and heart rate, or result in leg fatigue, or cause you to perspire.
[Show and read response card # 3]

FUP34

- A Not at all — Go to Item 36
- 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

FOLLOW-UP CONTACT FORM (FUPA Screen 18 of 21)

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

FUP35

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

36. 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]

FUP36

- 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

FOLLOW-UP CONTACT FORM (FUPA Screen 19 of 21)

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

FUP37

- 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

38. 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.)

FUP38

of flights

FOLLOW-UP CONTACT FORM (FUPA Screen 20 of 21)

H. SECOND BLOOD PRESSURE

39c. Indicate which arm:
(prefer same arm
as with first BP)

R Right

L Left

39. Seated Blood Pressure #2:

a. Systolic:

FUP39A

b. Diastolic:

FUP39B

FUP39C

FOLLOW-UP CONTACT FORM (FUPA Screen 21 of 21)

40. Average Blood Pressure:

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

BP variables found in rand_derv_niddkv1

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

If any hospitalizations or outpatient angioplasties were reported, complete Hospitalization Form.

If the patient is deceased, complete an Outcomes Documentation Form.

If the patient missed contact and is incapacitated, location is unknown or died, complete Informant Interview Form.

If this is a clinic visit, complete Medication Survey Form and Phlebotomy Form.

Schedule/Remind participant of next study contact.

41. Date of Data Collection:

/ /

Month Day Year

FUP41

42. Examiner's Initials:

Blind_staff_ID