

FAVORIT

RANDOMIZATION ELIGIBILITY FORM:

Folic Acid for Vascular Outcome
Reduction in Transplantation

FORM CODE: REL VERSION: D 03/03/05

ID NUMBER:

CONTACT OCCASION: 0 1

SEQUENCE NUMBER: 0 0

PATIENT LAST NAME:

FIRST/MIDDLE INITIALS:

INSTRUCTIONS: 1) FOR SCREENING/BASELINE COMBO - ALL BASELINE FORMS MUST BE ENTERED (MSR, PHC, PHP AND RPC) PRIOR TO COMPLETION OF THIS FORM 2) FOR THE SIMPLE SCREENING - PARTICIPANT MUST BE PRESENT TO COMPLETE THIS FORM

Randomization Visit Form: Eligibility (RELD Screen 1 of 9)

A. ELIGIBILITY CRITERIA

	<u>Yes</u>	<u>No</u>
[Determined by DMS]		
1. Is FAVORIT laboratory's screening total homocysteine (tHcy) level above the eligibility cut point?	Y	N REL4
[Determined by DMS]		
2. Is FAVORIT laboratory's screening creatinine clearance level above the eligibility cut point?	Y	N REL5
3. Age 35-75 years old:.....	Y	N REL6
4. Current kidney graft in place 6-months or longer:.....	Y	N REL7A

If "No", to either 1 through 4, patient is NOT eligible; go to item 23

Randomization Visit Form: Eligibility (RELD Screen 2 of 9)

	<u>Yes</u>	<u>No</u>
5. Has the participant had any transplants other than kidney or kidney-pancreas?.....	Y	N RELC5
If "YES", patient is NOT eligible; go to item 23		
6. Did the patient use any vitamin supplements (multivitamin, B-group vitamins, or individual vitamins) containing folic acid ("folate"), vitamin B6, or vitamin B12 during the past 4 weeks?.....	Y	N REL8

If "Yes", patient is NOT eligible; go to item 23

Randomization Visit Form: Eligibility (RELD Screen 3 of 9)

	<u>Yes</u>	<u>No</u>
7. Are there any of the following end stage or progressive conditions deemed to affect 2 year survivability.		
a. Cancer	Y*	N REL9A
b. End stage congestive heart failure/cardiomyopathy	Y*	N REL9B
c. End stage liver disease	Y*	N REL9C
d. End stage pulmonary disease	Y*	N REL9D
e. Progressive HIV	Y*	N REL9E
f. Any other chronic wasting illness	Y*	N REL9F
*If "Yes" patient is NOT eligible; go to item 23		

Randomization Visit Form: Eligibility (RELD Screen 4 of 9)

8. Sex:	M Male	Go to item 12	REL10
	F Female		
9. Is the patient ...		<u>Yes</u>	<u>No</u>
a. Pregnant?	Y*	N	REL11A
b. Lactating?	Y*	N	REL11B
*If "Yes", patient is NOT eligible; go to item 23			
10. Is the patient of childbearing potential?	Y	N	Go to item 12 REL12
11. Is the patient currently using birth control?	Y	N	REL13
If "No", patient is NOT eligible; go to item 23			

Randomization Visit Form: Eligibility (RELD Screen 5 of 9)

	<u>Yes</u>	<u>No</u>
12. Are there other conditions that prevent reliable participation in the study:		
a. Refractory depression	Y*	N REL14A
b. Severe cognitive impairment	Y*	N REL14B
c. Alcoholism or other substance abuse	Y*	N REL14C
13. Is the patient currently participating in any other study specifically involving cardiovascular disease risk factor management?.....	Y*	N REL15
14. Has the patient experienced a myocardial infarction (MI), stroke, percutaneous revascularization procedure (i.e., coronary, cerebrovascular, or lower extremity), or lower extremity amputation within the past 3 months?.....	Y*	N REL16

***IF "Yes", patient is NOT eligible; go to item 23**

Randomization Visit Form: Eligibility (RELD Screen 6 of 9)

	<u>Yes</u>	<u>No</u>
15. Has the patient had coronary artery bypass graft, abdominal aortic aneurysm repair or carotid endarterectomy within the past 6 months?	Y	N REL17
16. Since screening exam, has patient been hospitalized for renal graft dysfunction, or been told by their physician that their renal graft function has deteriorated?.....	Y	N REL18
17. Has patient returned to dialysis-dependence?.....	Y	N REL19
18. Is the randomization contact being conducted by telephone?.....	Y	N RELD18

IF "Yes", ALL Baseline forms must be collected during the screening visit

FAVORIT

RANDOMIZATION VISIT FORM: ELIGIBILITY

Folic Acid for Vascular Outcome
Reduction in Transplantation

FORM CODE: REL VERSION: C 05/08/03

ID NUMBER:

CONTACT OCCASION:

SEQUENCE NUMBER:

PATIENT LAST NAME:

FIRST/MIDDLE INITIALS:

Randomization Visit Form: Eligibility (RELC Screen 1 of 9)

TO COMPLETE THIS FORM PARTICIPANT MUST BE PRESENT

A. ELIGIBILITY CRITERIA

	<u>Yes</u>	<u>No</u>
[Determined by DMS]		
1. Is FAVORIT laboratory's screening total homocysteine (tHcy) level above the eligibility cut point?	Y	N REL4
[Determined by DMS]		
2. Is FAVORIT laboratory's screening creatinine clearance 30 mL/min or greater?	Y	N REL5
3. Age 35-75 years old:.....	Y	N REL6
4. Current kidney graft in place 6-months or longer:.....	Y	N REL7A

If "No", to either 1 through 4, patient is NOT eligible; go to item 22

Randomization Visit Form: Eligibility (RELC Screen 2 of 9)

	<u>Yes</u>	<u>No</u>
5. Has the participant had any transplants other than kidney or kidney-pancreas?.....	Y	N RELC5
If "YES", patient is NOT eligible; go to item 22		
6. Did the patient use any vitamin supplements (multivitamin, B-group vitamins, or individual vitamins) containing folic acid ("folate"), vitamin B6, or vitamin B12 during the past 4 weeks?.....	Y	N REL8
If "Yes", patient is NOT eligible; go to item 22		

Randomization Visit Form: Eligibility (RELC Screen 3 of 9)

	<u>Yes</u>	<u>No</u>
7. Are there any of the following end stage or progressive conditions deemed to affect 2 year survivability.		
a. Cancer	Y*	N REL9A
b. End stage congestive heart failure/cardiomyopathy	Y*	N REL9B
c. End stage liver disease	Y*	N REL9C
d. End stage pulmonary disease	Y*	N REL9D
e. Progressive HIV	Y*	N REL9E
f. Any other chronic wasting illness	Y*	N REL9F
*If "Yes" patient is NOT eligible; go to item 22		

Randomization Visit Form: Eligibility (RELC Screen 4 of 9)

8. Sex:	M Male	Go to item 12	
	F Female		REL10
9. Is the patient ...		<u>Yes</u>	<u>No</u>
a. Pregnant?	Y*	N	REL11A
b. Lactating?	Y*	N	REL11B
*If "Yes", patient is NOT eligible; go to item 22			
10. Is the patient of childbearing potential?	Y	N	Go to item 12 REL12
11. Is the patient currently using birth control?	Y	N	REL13
If "No", patient is NOT eligible; go to item 22			

Randomization Visit Form: Eligibility (RELC Screen 5 of 9)

	<u>Yes</u>	<u>No</u>	
12. Are there other conditions that prevent reliable participation in the study:			
a. Refractory depression	Y*	N	REL14A
b. Severe cognitive impairment	Y*	N	REL14B
c. Alcoholism or other substance abuse	Y*	N	REL14C
13. Is the patient currently participating in any other study specifically involving cardiovascular disease risk factor management?.....	Y*	N	REL15
14. Has the patient experienced a myocardial infarction (MI), stroke, percutaneous revascularization procedure (i.e., coronary, cerebrovascular, or lower extremity), or lower extremity amputation within the past 3 months?.....	Y*	N	REL16
*IF "Yes", patient is NOT eligible; go to item 22			

Randomization Visit Form: Eligibility (RELC Screen 6 of 9)

	<u>Yes</u>	<u>No</u>	
15. Has the patient had coronary artery bypass graft, abdominal aortic aneurysm repair or carotid endarterectomy within the past 6 months?	Y	N	REL17
IF "Yes", patient is NOT eligible; go to item 22			
16. Since screening exam, has patient been hospitalized for renal graft dysfunction, or been told by their physician that their renal graft function has deteriorated?.....	Y	N	REL18
IF "Yes", patient is NOT eligible; go to item 22			
17. Has patient returned to dialysis-dependence?	Y	N	REL19
IF "Yes", patient is NOT eligible; go to item 22			

FAVORIT

RANDOMIZATION VISIT FORM: ELIGIBILITY

Folic Acid for Vascular Outcome
Reduction in Transplantation

FORM CODE: REL VERSION: B 11/04/02

ID NUMBER:

CONTACT OCCASION: 0 1

SEQUENCE NUMBER: 0 0

PATIENT LAST NAME:

FIRST/MIDDLE INITIALS:

Randomization Visit Form: Eligibility (RELB Screen 1 of 10)

A. DEMOGRAPHICS

1. Date of birth: / / **REL1**
Month Day Year

2. How would you describe your racial background? If you have a mixed background, please indicate all that apply.

	<u>Yes</u>	<u>No</u>	
a. American Indian or Alaska Native	Y	N	REL2A
b. Asian	Y	N	REL2B
c. Black or African American	Y	N	REL2C
d. Native Hawaiian or Other Pacific Islander	Y	N	REL2D
e. White	Y	N	REL2E

**REL1 - 3 Moved
to SPC 4/11/03**

Randomization Visit Form: Eligibility (RELB Screen 2 of 10)

3. Which of the following best describes your ethnic identification:

- H Hispanic or Latino **REL3**
- N Neither Hispanic nor Latino

B. ELIGIBILITY CRITERIA

[Determined by DMS] Yes No

4. Is FAVORIT laboratory's screening total homocysteine (tHcy) level above the eligibility cut point? Y **REL4** N

[Determined by DMS]

5. Is FAVORIT laboratory's screening creatinine clearance 30 mL/min or greater? Y **REL5** N

6. Age 35-75 years old: Y **REL6** N

If "No", to either 4, 5, or 6, patient is NOT eligible; go to item 24

Randomization Visit Form: Eligibility (RELB Screen 3 of 10)

	<u>Yes</u>	<u>No</u>	
7a. Current graft in place 6-months or longer:	Y	N	REL7A
If "No", patient is NOT eligible; go to item 24			
b. Was the graft from a living donor or from a cadaver donor?			RELB7B
L Living related donor			Moved to SPC 4/11/03
U Living unrelated donor			
C Cadaver donor			
8. Did the patient use any vitamin supplements (multivitamin, B-group vitamins, or individual vitamins) containing folic acid ("folate"), vitamin B6, or vitamin B12 during the past 4 weeks?.....	Y	N	REL8
If "Yes", patient is NOT eligible; go to item 24			

Randomization Visit Form: Eligibility (RELB Screen 4 of 10)

	<u>Yes</u>	<u>No</u>	
9. Are there any of the following end stage or progressive conditions deemed to affect 2 year survivability.			
a. Cancer	Y*	N	REL9A
b. End stage congestive heart failure/cardiomyopathy	Y*	N	REL9B
c. End stage liver disease	Y*	N	REL9C
d. End stage pulmonary disease	Y*	N	REL9D
e. Progressive HIV	Y*	N	REL9E
f. Any other chronic wasting illness	Y*	N	REL9F
*If "Yes" patient is NOT eligible; go to item 24			

Randomization Visit Form: Eligibility (RELB Screen 5 of 10)

10. Sex:			
M Male	Go to item 14		REL10
F Female			
11. Is the patient ...			
a. Pregnant?	Y*	N	REL11A
b. Lactating?	Y*	N	REL11B
If "Yes", patient is NOT eligible; go to item 24			
12. Is the patient of childbearing potential?	Y	N	REL12
13. Is the patient currently using birth control?	Y	N	REL13
If "No", patient is NOT eligible; go to item 24			

Randomization Visit Form: Eligibility (RELB Screen 6 of 10)

	<u>Yes</u>	<u>No</u>
14. Are there other conditions that prevent reliable participation in the study:		
a. Refractory depression	Y*	N REL14A
b. Severe cognitive impairment	Y*	N REL14B
c. Alcoholism or other substance abuse	Y*	N REL14C
15. Is the patient currently participating in any other study specifically involving cardiovascular disease risk factor management?.....	Y*	N REL15
16. Has the patient experienced a myocardial infarction (MI), stroke, percutaneous revascularization procedure (i.e., coronary, cerebrovascular, or lower extremity), or lower extremity amputation within the past 3 months?.....	Y*	N REL16

***IF "Yes", patient is NOT eligible; go to item 24**

Randomization Visit Form: Eligibility (RELB Screen 7 of 10)

	<u>Yes</u>	<u>No</u>
17. Has the patient had coronary artery bypass graft or abdominal aortic aneurysm repair within the past 6 months?.....	Y	N REL17
*IF "Yes", patient is NOT eligible; go to item 24		
18. Since screening exam, has patient been hospitalized for renal graft dysfunction, or been told by their physician that their renal graft function has deteriorated?.....	Y	N REL18
*IF "Yes", patient is NOT eligible; go to item 24		
19. Has patient returned to dialysis-dependence?	Y	N REL19
*IF "Yes", patient is NOT eligible; go to item 24		

Randomization Visit Form: Eligibility (RELB Screen 8 of 10)

C. RANDOMIZATION

20. Date of randomization:

		/			/				
Month			Day			Year			

See rand_derv_niddkv1 for final date of randomization

REL20

21. Do you want to randomize this patient?

Y Yes

N No — Go to item 24

REL20

NOTE: DMS will determine the number of days from screening to date of randomization. If this is > 120 days the patient is NOT eligible. (See Eligibility Report for results)

Randomization Visit Form: Eligibility (RELB Screen 9 of 10)

The DMS has identified a discrepancy between the date of randomization entered in item 20 and the computer date. Please confirm the date of randomization (date the DMS will be assigning the bottle code).

See rand_derv_niddkv1 for final date of randomization

22a. Confirmation of date of randomization:

		/			/				
Month			Day			Year			

If confirmed date of randomization matches computer date, skip to item 22c. REL22A

22b. Date in item 22a disagrees with the "Computer Date". Explain the discrepancy and contact the DCC immediately following completion of the participant visit: _____

REL24B

22c. Do you want to randomize this patient?

Y Yes

N No — Go to item 24

REL22C

Randomization Visit Form: Eligibility (RELB Screen 10 of 10)

[Determined by DMS]

23. Bottle code assigned by Data Management System:

REL21

D. ADMINISTRATIVE INFORMATION

24. Date of data collection:

		/			/				
Month			Day			Year			

REL25

25. Initials of data collector:

Blind_staff_ID

If patient is randomized, distribute vitamins and complete the Vitamin Distribution Log, complete the Participant Update Form and proceed to Medication Listing/Medication Survey Form

FAVORIT

RANDOMIZATION VISIT FORM: ELIGIBILITY

Folic Acid for Vascular Outcome
Reduction in Transplantation

FORM CODE: REL VERSION: A 02/18/02

ID NUMBER:

CONTACT OCCASION: 0 1

SEQUENCE NUMBER: 0 0

PATIENT LAST NAME:

FIRST/MIDDLE INITIALS:

Randomization Visit Form: Eligibility (RELA Screen 1 of 9)

A. DEMOGRAPHICS

1. Date of birth: / /
Month Day Year REL1

2. How would you describe your racial background? If you have a mixed background, please indicate all that apply.

	<u>Yes</u>	<u>No</u>	
a. American Indian or Alaska Native	Y	N	REL2A
b. Asian	Y	N	REL2B
c. Black or African American	Y	N	REL2C
d. Native Hawaiian or Other Pacific Islander	Y	N	REL2D
e. White	Y	N	REL2E

REL1 - 3 Moved
to SPC 4/11/03

Randomization Visit Form: Eligibility (RELA Screen 2 of 9)

3. Which of the following best describes your ethnic identification: REL3

H Hispanic or Latino

N Neither Hispanic nor Latino

B. ELIGIBILITY CRITERIA

	<u>Yes</u>	<u>No</u>	
[Determined by DMS]			
4. Is FAVORIT laboratory's screening total homocysteine (tHcy) level above the eligibility cut point?	Y	N	REL4
[Determined by DMS]			
5. Is FAVORIT laboratory's screening creatinine clearance 30 mL/min or greater?	Y	N	REL5
6. Age 35-75 years old:.....	Y	N	REL6

If "No", to either 4, 5, or 6, patient is NOT eligible; go to item 25

Randomization Visit Form: Eligibility (RELA Screen 3 of 9)

	<u>Yes</u>	<u>No</u>	
7a. Current graft in place 6-months or longer:	Y	N	REL7A
If "No", patient is NOT eligible; go to item 25			
b. Was the graft from a living related donor or from a cadaver donor?			RELA7B
L Living related donor			
C Cadaver donor			
8. Did the patient use any vitamin supplements (multivitamin, B-group vitamins, or individual vitamins) containing folic acid ("folate"), vitamin B6, or vitamin B12 during the past 4 weeks?.....	Y	N	REL8
If "Yes", patient is NOT eligible; go to item 25			

Randomization Visit Form: Eligibility (RELA Screen 4 of 9)

	<u>Yes</u>	<u>No</u>	
9. Are there any of the following end stage or progressive conditions deemed to affect 2 year survivability.			
a. Cancer	Y*	N	REL9A
b. End stage congestive heart failure/cardiomyopathy	Y*	N	REL9B
c. End stage liver disease	Y*	N	REL9C
d. End stage pulmonary disease	Y*	N	REL9D
e. Progressive HIV	Y*	N	REL9E
f. Any other chronic wasting illness	Y*	N	REL9F
*If "Yes" patient is NOT eligible; go to item 25			

Randomization Visit Form: Eligibility (RELA Screen 5 of 9)

10. Sex:			REL10
M Male	—	Go to item 14	
F Female			
11. Is the patient ...			
a. Pregnant?	Y*	N	REL11A
b. Lactating?	Y*	N	REL11B
If "Yes", patient is NOT eligible; go to item 25			
12. Is the patient of childbearing potential?	Y	N	REL12
13. Is the patient currently using birth control?	Y	N	REL13
If "No", patient is NOT eligible; go to item 25			

Randomization Visit Form: Eligibility (RELA Screen 6 of 9)

	<u>Yes</u>	<u>No</u>
14. Are there other conditions that prevent reliable participation in the study:		
a. Refractory depression	Y*	N REL14A
b. Severe cognitive impairment	Y*	N REL14B
c. Alcoholism or other substance abuse	Y*	N REL14C
15. Is the patient currently participating in any other study specifically involving cardiovascular disease risk factor management?.....	Y*	N REL15
16. Has the patient experienced a myocardial infarction (MI), stroke, percutaneous revascularization procedure (i.e., coronary, cerebrovascular, or lower extremity), or lower extremity amputation within the past 3 months?.....	Y*	N REL16

IF "Yes", patient is NOT eligible; go to item 25

Randomization Visit Form: Eligibility (RELA Screen 7 of 9)

	<u>Yes</u>	<u>No</u>
17. Has the patient had coronary artery bypass graft or abdominal aortic aneurysm repair within the past 6 months?.....	Y	N REL17
IF "Yes", patient is NOT eligible; go to item 25		
18. Since screening exam, has patient been hospitalized for renal graft dysfunction, or been told by their physician that their renal graft function has deteriorated?.....	Y	N REL18
IF "Yes", patient is NOT eligible; go to item 25		
19. Has patient returned to dialysis-dependence?	Y	N REL19
IF "Yes", patient is NOT eligible; go to item 25		

C. RANDOMIZATION

20. Do you want to randomize this patient?.....	Y	N REL20
If "No", go to item 25		

21. Bottle code assigned by Data Management System:	<input type="text"/> <input type="text"/>	REL21
---	---	---

[Determined by DMS]

See rand_derv_niddkv1
for final date of
randomization

Randomization Visit Form: Eligibility (RELA Screen 8 of 9)

[Determined by DMS]

22. Date of randomization:

		/			/			
Month			Day			Year		

RELA22

23. Is the date in question 22 the correct date of randomization (date bottle code is first assigned)?

RELA23

Y Yes Go to item 25

N No

CONTACT THE DCC IMMEDIATELY REGARDING DATE OF RANDOMIZATION DISCREPANCY

24a. What is the correct date of randomization?

		/			/			
Month			Day			Year		

RELA24A

REL24B

b. Explain the discrepancy in dates: _____

Randomization Visit Form: Eligibility (RELA Screen 9 of 9)

D. ADMINISTRATIVE INFORMATION

25. Date of data collection:

		/			/			
Month			Day			Year		

REL25

26. Initials of data collector:

--	--	--	--

Blind_staff_ID

If patient is randomized,
distribute vitamins and complete the Vitamin Distribution Log,
complete the Participant Update Form
and proceed to Medication Listing/Medication Survey Form