

FAVORIT

Folic Acid for Vascular Outcome
Reduction in Transplantation

INFORMANT INTERVIEW FORM

FORM CODE: INF VERSION: B 03/18/03

ID NUMBER:

CONTACT OCCASION:

SEQUENCE NUMBER:

PATIENT LAST NAME:

FIRST/MIDDLE INITIALS:

INFORMANT INTERVIEW FORM (INFB Screen 1 of 13)

A. VITAMINS

INF1

1. Over the past six months, did the participant take the study vitamins?

- A Yes, at least 75% of the time
- B Yes, approximately 25% to 75% of the time
- C Seldom, less than 25% of the time
- D No, did not take study vitamin
- E Unknown —

INFORMANT INTERVIEW FORM (INFB Screen 2 of 13)

2. Can a pill count be performed:

INF2

- Y Yes
- N No —

3. Was the study vitamin taken today
(or on day of death if participant
is deceased)?

INF3

- Y Yes
- N No
- U Unknown

See adher_niddkv1
for medication
adherence.

4. Total number of bottles dispensed
to the participant since the last
pill count:

INF4

5. Total number of pills remaining:

INF5

6. Other than the assigned study
vitamin, is the participant
currently (or was at the time of
death) using any vitamin
supplements (multivitamin, B-group,
vitamins, or individual vitamins)
containing folic acid ("folate"),
vitamin B6, or vitamin B12?

INF6

- Y Yes
- N No —
- U Unknown —

7. Is he/she taking?

Yes No

- a. Folic acid Y N
- b. Vitamin B6 Y N
- c. Vitamin B12 Y N

INF7A

INF7B

INF7C

INFORMANT INTERVIEW FORM (INFB Screen 3 of 13)

B. VITAMIN SIDE EFFECTS

8. Since <date of last contact>, did the participant experience any side effects that may be associated with the vitamins?

INF8

Y Yes

N No — Go to Item 10

U Unknown — Go to Item 10

INFORMANT INTERVIEW FORM (INFB Screen 4 of 13)

9. What side effects did the participant experience? [Do not probe specific symptoms, but record yes or no to items a-f based on informant's response]

Yes No

a. Itching Y N INF9A

b. Gastrointestinal Disturbances Y N INF9B

c. Headache Y N INF9C

d. Fatigue Y N INF9D

e. Change in appetite or weight Y N INF9E

f. Other significant side effects Y N — Go to Item 10 INF9F

Specify other significant side effects _____

INFORMANT INTERVIEW FORM (INFB Screen 5 of 13)

C. HOSPITALIZATION AND PROCEDURE HISTORY

INF10

10. Was the participant hospitalized since <date of last contact>? [If so, coordinator requests hospital name & address for follow-up]

Y Yes — Complete Hospitalization Form upon completion of this form

N No — Go to Item 12

U Unknown — Go to Item 12

11. Record the approximate date of the hospital admission(s):

a. [] [] / [] [] / [] [] [] []
Month Day Year INF11A

b. [] [] / [] [] / [] [] [] []
Month Day Year INF11B

c. [] [] / [] [] / [] [] [] []
Month Day Year INF11C

INFORMANT INTERVIEW FORM (INFB Screen 6 of 13)

12. Since <date of last contact>, did the participant undergo angioplasty of the lower extremity arteries, renal arteries, or coronary arteries as an outpatient? INF12

Y Yes — Complete Hospitalization Form upon completion of this form

N No — Go to Item 14

U Unknown — Go to Item 14

13. Record the approximate date of the outpatient angioplasty(s):

a. / / INF13A
 Month Day Year

b. / / INF13B
 Month Day Year

c. / / INF13C
 Month Day Year

INFORMANT INTERVIEW FORM (INFB Screen 7 of 13)

14. Since <date of last contact>, did the participant undergo outpatient carotid artery endarterectomy or carotid artery angioplasty? INF14

Y Yes — Complete Hospitalization Form upon completion of this form

N No — Go to Item 16

U Unknown — Go to Item 16

15. Record the approximate date of the carotid artery endarterectomy(s) or carotid artery angioplasty(s):

a. / / INF15A
 Month Day Year

b. / / INF15B
 Month Day Year

c. / / INF15C
 Month Day Year

INFORMANT INTERVIEW FORM (INFB Screen 8 of 13)

16. Since <date of last contact>, did the participant re-initiate dialysis? INF16

Y Yes

N No — Go to Item 18

U Unknown — Go to Item 18

17. Record the approximate date the participant re-initiated dialysis: INF17

 / /
 Month Day Year

INFORMANT INTERVIEW FORM (INFB Screen 9 of 13)

D. DEATH

18. Is the participant deceased? INF18

Y Yes — Complete Outcomes Documentation Form upon completion of this form

N No — Go to Item 29

U Unknown — Go to Item 29

19. Date of death: INF19

		/			/				
Month			Day			Year			

INFORMANT INTERVIEW FORM (INFB Screen 10 of 13)

20. Presumed cause of death:

_____ INF20A

_____ INF20B

_____ INF20C

INFORMANT INTERVIEW FORM (INFB Screen 11 of 13)

21. Location of death:

A In hospital — Complete Hospitalization Form
Go to Item 29

B In emergency room INF21

C En route to hospital

D At home

E At work

F Unknown

G Other

If other specify: _____

22. An "Event Packet ID" must be assigned/used whenever an Out-of-Hospital death occurs. The same Event Packet ID must be used on the corresponding OUT form.

Record appropriate FAVORIT Event Packet ID:

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INF23

23. Was death witnessed? INF22

Y Yes — Go to Item 26

N No

U Unknown — Go to Item 26

INFORMANT INTERVIEW FORM (INFB Screen 12 of 13)

<p>24. How long had it been since the participant was seen alive? INF24</p> <p>A <1 hour</p> <p>B 1 hour to <24 hours</p> <p>C ≥ 24 hours</p> <p>D Unknown</p>	<p>27. Was emergency resuscitation attempted? INF27</p> <p>Y Yes</p> <p>N No</p> <p>U Unknown</p>
<p>25. Was the participant found in bed? INF25</p> <p>Y Yes</p> <p>N No</p> <p>U Unknown</p>	<p>28. Considering the participant's condition in the days and hours prior to death, was the death clinically expected? INF28</p> <p>Y Yes</p> <p>N No</p> <p>U Unknown</p>
<p>26. Was the participant receiving hospice care? INF26</p> <p>Y Yes</p> <p>N No</p> <p>U Unknown</p>	

INFORMANT INTERVIEW FORM (INFB Screen 13 of 13)

E. ADMINISTRATIVE INFORMATION

<p>29. Informant source: INF29</p> <p>A Spouse</p> <p>B Parent</p> <p>C Daughter/Son</p> <p>D Other relative</p> <p>E Friend</p> <p>F Workmate</p> <p>G Physician</p> <p>H Other healthcare practitioner</p> <p>I Other</p> <p>If other, specify: _____</p> <p>_____</p>	<p>30. In this interviewer's opinion, is the information provided by this informant reliable? INF30</p> <p>A Very reliable</p> <p>B Somewhat reliable</p> <p>C Unreliable</p>																				
	<p>31. Date of data collection: INF31</p> <table border="1" style="width: 100%; text-align: center;"> <tr> <td style="width: 20px;"> </td> <td style="width: 20px;"> </td> <td style="width: 20px;">/</td> <td style="width: 20px;"> </td> <td style="width: 20px;"> </td> <td style="width: 20px;">/</td> <td style="width: 20px;"> </td> <td style="width: 20px;"> </td> <td style="width: 20px;"> </td> <td style="width: 20px;"> </td> </tr> <tr> <td colspan="3">Month</td> <td colspan="3">Day</td> <td colspan="4">Year</td> </tr> </table>			/			/					Month			Day			Year			
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INFORMANT INTERVIEW FORM (INFA Screen 2 of 13)

2. Can a pill count be performed:

- Y Yes
- N No —

INF2

3. Was the study vitamin taken today
(or on day of death if participant
is deceased)?

- Y Yes
- N No
- U Unknown

INF3

See adher_niddkv1
for medication
adherence.

4. Total number of bottles dispensed
to the participant since the last
pill count:

INF4

5. Total number of pills remaining:

INF5

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

- Y Yes
- N No —
- U Unknown —

INF6

7. Is he/she taking:

Yes No

- a. Folic acid Y N
- b. Vitamin B6 Y N
- c. Vitamin B12 Y N

INFORMANT INTERVIEW FORM (INFA Screen 3 of 13)

B. VITAMIN SIDE EFFECTS

8. Since <date of last contact>, did the participant experience any side effects that may be associated with the vitamins?

INF8

Y Yes

N No — Go to Item 10

U Unknown — Go to Item 10

INFORMANT INTERVIEW FORM (INFA Screen 4 of 13)

9. What side effects did the participant experience? [Do not probe specific symptoms, but record yes or no to items a-f based on informant's response]

Yes No

a. Itching Y N INF9A

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d. Fatigue Y N INF9D

e. Change in appetite or weight Y N INF9E

f. Other significant side effect Y N — Go to Item 10 INF9F

Specify other significant side effect _____

INFORMANT INTERVIEW FORM (INFA Screen 5 of 13)

C. HOSPITALIZATION AND PROCEDURE HISTORY

INF10

10. Was the participant hospitalized since <date of last contact>? [If so, coordinator requests hospital name & address for follow-up]

Y Yes — Complete Hospitalization Form upon completion of this form

N No — Go to Item 12

U Unknown — Go to Item 12

11. Record the approximate date of the hospital admission(s):

a. [] [] / [] [] / [] [] [] [] INF11A
Month Day Year

b. [] [] / [] [] / [] [] [] [] INF11B
Month Day Year

c. [] [] / [] [] / [] [] [] [] INF11C
Month Day Year

INFORMANT INTERVIEW FORM (INFA Screen 6 of 13)

<p>12. Since <date of last contact>, did the participant undergo angioplasty of the lower extremity arteries, renal arteries, or coronary arteries as an outpatient? INF12</p> <p>Y Yes — <div style="border: 1px solid black; padding: 5px; display: inline-block;">Complete Hospitalization Form upon completion of this form</div></p> <p>N No — <div style="border: 1px solid black; padding: 5px; display: inline-block;">Go to Item 14</div></p> <p>U Unknown — <div style="border: 1px solid black; padding: 5px; display: inline-block;">Go to Item 14</div></p>	<p>13. Record the approximate date of the outpatient angioplasty(s):</p> <p>a. <table border="1" style="display: inline-table; border-collapse: collapse; text-align: center;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px; border: none;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px; border: none;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> <tr><td colspan="2">Month</td><td colspan="2">Day</td><td colspan="6">Year</td></tr> </table> INF13A</p> <p>b. <table border="1" style="display: inline-table; border-collapse: collapse; text-align: center;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px; border: none;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px; border: none;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> <tr><td colspan="2">Month</td><td colspan="2">Day</td><td colspan="6">Year</td></tr> </table> INF13B</p> <p>c. <table border="1" style="display: inline-table; border-collapse: collapse; text-align: center;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px; border: none;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px; border: none;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> <tr><td colspan="2">Month</td><td colspan="2">Day</td><td colspan="6">Year</td></tr> </table> INF13C</p>			/			/					Month		Day		Year								/			/					Month		Day		Year								/			/					Month		Day		Year					
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INFORMANT INTERVIEW FORM (INFA Screen 7 of 13)

<p>14. Since <date of last contact>, did the participant undergo outpatient carotid artery endarterectomy or carotid artery angioplasty? INF14</p> <p>Y Yes — <div style="border: 1px solid black; padding: 5px; display: inline-block;">Complete Hospitalization Form upon completion of this form</div></p> <p>N No — <div style="border: 1px solid black; padding: 5px; display: inline-block;">Go to Item 16</div></p> <p>U Unknown — <div style="border: 1px solid black; padding: 5px; display: inline-block;">Go to Item 16</div></p>	<p>15. Record the approximate date of the carotid artery endarterectomy(s) or carotid artery angioplasty(s):</p> <p>a. <table border="1" style="display: inline-table; border-collapse: collapse; text-align: center;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px; border: none;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px; border: none;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> <tr><td colspan="2">Month</td><td colspan="2">Day</td><td colspan="6">Year</td></tr> </table> INF15A</p> <p>b. <table border="1" style="display: inline-table; border-collapse: collapse; text-align: center;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px; border: none;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px; border: none;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> <tr><td colspan="2">Month</td><td colspan="2">Day</td><td colspan="6">Year</td></tr> </table> INF15B</p> <p>c. <table border="1" style="display: inline-table; border-collapse: collapse; text-align: center;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px; border: none;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px; border: none;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> <tr><td colspan="2">Month</td><td colspan="2">Day</td><td colspan="6">Year</td></tr> </table> INF15C</p>			/			/					Month		Day		Year								/			/					Month		Day		Year								/			/					Month		Day		Year					
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INFORMANT INTERVIEW FORM (INFA Screen 8 of 13)

<p>16. Since <date of last contact>, did the participant re-initiate dialysis? INF16</p> <p>Y Yes</p> <p>N No — <div style="border: 1px solid black; padding: 5px; display: inline-block;">Go to Item 18</div></p> <p>U Unknown — <div style="border: 1px solid black; padding: 5px; display: inline-block;">Go to Item 18</div></p>	<p>17. Record the approximate date the participant re-initiated dialysis: INF17</p> <p><table border="1" style="display: inline-table; border-collapse: collapse; text-align: center;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px; border: none;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px; border: none;">/</td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> <tr><td colspan="2">Month</td><td colspan="2">Day</td><td colspan="6">Year</td></tr> </table></p>			/			/					Month		Day		Year					
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INFORMANT INTERVIEW FORM (INFA Screen 9 of 13)

D. DEATH

18. Is the participant deceased? INF18

Y Yes — Complete Outcomes Documentation Form upon completion of this form

N No — Go to Item 29

U Unknown — Go to Item 29

19. Date of death: INF19

		/			/				
Month			Day			Year			

INFORMANT INTERVIEW FORM (INFA Screen 10 of 13)

20. Presumed cause of death:

_____ INF20A

_____ INF20B

_____ INF20C

INFORMANT INTERVIEW FORM (INFA Screen 11 of 13)

21. Location of death:

A In hospital — Complete Hospitalization Form
Go to Item 29

B In emergency room INF21

C En route to hospital

D At home

E At work

F Unknown

G Other

If other specify: _____

22. Was death witnessed? INF22

Y Yes — Go to Item 26

N No

U Unknown — Go to Item 26

23. An "Event Packet ID" must be assigned/used whenever an Out-of-Hospital death occurs. The same Event Packet ID must be used on the corresponding OUT form.

Record appropriate FAVORIT Event Packet ID:

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INF23

INFORMANT INTERVIEW FORM (INFA Screen 12 of 13)

<p>24. How long had it been since the participant was seen alive? INF24</p> <p>A <1 hour</p> <p>B 1 hour to <24 hours</p> <p>C ≥ 24 hours</p> <p>D Unknown</p> <p>25. Was the participant found in bed? INF25</p> <p>Y Yes</p> <p>N No</p> <p>U Unknown</p> <p>26. Was the participant receiving hospice care? INF26</p> <p>Y Yes</p> <p>N No</p> <p>U Unknown</p>	<p>27. Was emergency resuscitation attempted? INF27</p> <p>Y Yes</p> <p>N No</p> <p>U Unknown</p> <p>28. Considering the participant's condition in the days and hours prior to death, was the death clinically expected? INF28</p> <p>Y Yes</p> <p>N No</p> <p>U Unknown</p>
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INFORMANT INTERVIEW FORM (INFA Screen 13 of 13)

E. ADMINISTRATIVE INFORMATION

<p>29. Informant source: INF29</p> <p>A Spouse</p> <p>B Parent</p> <p>C Daughter/Son</p> <p>D Other relative</p> <p>E Friend</p> <p>F Workmate</p> <p>G Physician</p> <p>H Other healthcare practitioner</p> <p>I Other</p> <p>If other, specify: _____</p> <p>_____</p>	<p>30. In this interviewer's opinion, is the information provided by this informant reliable? INF30</p> <p>A Very reliable</p> <p>B Somewhat reliable</p> <p>C Unreliable</p> <p>31. Date of data collection: INF31</p> <table border="1" style="margin-left: 20px;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">/</td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">/</td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td colspan="3" style="text-align: center;">Month</td> <td colspan="3" style="text-align: center;">Day</td> <td colspan="4" style="text-align: center;">Year</td> </tr> </table> <p>32. Interviewer's Initials:</p> <table border="1" style="margin-left: 20px;"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="border: 1px solid red; padding: 2px;">Blind_staff_ID</td> </tr> </table>			/			/					Month			Day			Year							Blind_staff_ID
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