FAVORIT

Folic Acid for Vascular Outcome Reduction in Transplantation

INFORMED CONSENT MODIFICATIONS OR WITHDRAWAL FORM

FORM CODE: ICM VERSION: C 8/17/09

ID NUMBER: | | | | | | | | CONTACT OCCASION: | | SEQUENCE NUMBER: | |

PATIENT LAST NAME: | | | | | | | | | | | | FIRST/MIDDLE INITIALS: | |

Informed Consent Modifications or Withdrawal Form (ICMC Screen 1 of 7)

1. Purpose of completing this form: ICMB1

   C Consent for extended follow-up

   W Withdraw — Go to Item 14

   R Reinstated after withdraw — Go to Item 15

   O Other consent change — Go to Item 6

   L Consent for closure and extended contact — Go to Item 16

2. Has participant agreed to extend follow-up past 5 years? ICMB2

   Y Yes

   N No — Go to Item 4

3. Date participant signed consent to extend follow-up: ICMB3

   | | | / | | | / | | | | |

   Month Day Year

   Go to item 6

4. Reason why participant will not extend follow-up past 5 years: ICMB4

   T Time burden

   S Side effects from study vitamins

   M Medical condition (kidney failure, etc)

   O Other

   If other, specify reason for not extending follow-up period past 5 years:

   _____

5. Did the site principal investigator talk to the participant about the importance of extending follow-up? ICMB5

   Y Yes

   N No — Go to Item 28

Informed Consent Modifications or Withdrawal Form (ICMC Screen 2 of 7)

6. Are there any restrictions on use/storage of DNA? ICM3

   Y Yes

   N No — Go to Item 8

7. Type of restriction on use/storage of DNA: ICM4

   C Use for CVD or renal research only

   F Use for FAVORIT study only

   N No use/storage of DNA

   O Other

   If other, specify details of DNA restriction:

   _____

8. Are there any restrictions on stored (archived) blood? ICM5

   Y Yes

   N No — Go to item 10

9. Type of restriction on stored (archived) blood: ICM6

   C Use for CVD or renal research only

   F Use for FAVORIT study only

   N No use/storage of archived blood

   O Other

   If other, specify details of stored blood restrictions:_____

ID_____ CO_____ Seq No_____

Informed Consent Modifications or Withdrawal Form (ICMC Screen 3 of 7)

10. Are there any restrictions on stored (archived) urine? ICM7

Y Yes

N No — Go to item 12

11. Type of restriction on stored (archived) urine: ICM8

C Use for CVD or renal research only

F Use for FAVORIT study only

N No use/storage of urine

O Other

If other, specify details of stored urine restriction:

_____

12. Has permission been granted to access medical records? ICM9

Y Yes, full access

N No access

P Partial access

If partial, specify details:

_____

13. Has permission been granted to contact informants? ICM10

Y Yes, full contact

N No contact

L Limited contact

If limited, specify details:

_____

Go to item 28

Informed Consent Modifications or Withdrawal Form (ICMC Screen 4 of 7)

14. Date of withdrawal request: ICM12

		/			/				

Month Day Year

Go to item 28

15. Date reinstated: ICMB15

		/			/				

Month Day Year

Go to item 28

16. Has participant signed consent for closure and extended contact? ICMC16

Y Yes

N No — Go to Item 26

17. Date participant signed consent for closure and extended contact: ICMC17

		/			/				

Month Day Year

18. Type of consent: ICMC18

F Full — Go to Item 28

P Partial

19. Are there restrictions on contacting the participant to receive study results? ICMC19

Y Yes

N No — Go to Item 21

20. Contact regarding receiving study results to be made by: ICMC20

N Participant does not want to be contacted

S Participant wants contact only by clinical site

O Other

If Other, specify details:

_____

ID_____ CO_____ Seq No_____

Informed Consent Modifications or Withdrawal Form (ICMC Screen 5 of 7)

21. Are there restrictions on contacting the participant to give them their treatment arm (high/low dose)? ICMC21

Y Yes

N No — Go to Item 23

22. Contact regarding treatment arm to be made by: ICMC22

N Participant does not want to be contacted

S Participant wants contact only by clinical site

O Other

If Other, specify details:

_____

23. Are there restrictions on contacting the participant regarding future studies? ICMC23

Y Yes

N No — Go to Item 25

24. Contact regarding future studies to be made by: ICMC24

N Participant does not want to be contacted

S Participant wants contact only by clinical site

O Other

If Other, specify details:

_____

Informed Consent Modifications or Withdrawal Form (ICMC Screen 6 of 7)

25. Participant consented to allow linkage to NDI, UNOS, USRDS, or equivalents: ICMC25

Y Yes

P Partial

N No

If Partial, specify details:

_____

Go to Item 28

26. Did the participant receive the consent via mail? ICMC26

Y Yes, trackable mail

R Yes, other mail

N No

27. Reason why participant did not sign consent for closure and extended contact: ICMC27

A After repeated attempts, unable to contact participant to determine reason for not signing consent

D Did not attempt to contact participant

M Medical condition/incapacitated

N Participant not interested

U Participant did not give a reason

O Other

If other, specify reason for not signing closure/extended consent:

_____

ID_____ **CO**_____ **Seq No**_____

Informed Consent Modifications or Withdrawal Form (ICMC Screen 7 of 7)

28. Method of data collection: ICMB16

C Computer

P Paper

29. Date of data collection:

		/			/					ICMB17
Month			Day			Year				

30. Initials of staff person revising consent status: Blind_Staff_ID

See Screen_derv_niddkv1 for FINAL consent status

FAVORIT

Folic Acid for Vascular Outcome Reduction in Transplantation

INFORMED CONSENT MODIFICATIONS OR WITHDRAWAL FORM

FORM CODE: ICM VERSION: B 2/14/07

ID NUMBER: | | | | | | | | CONTACT OCCASION: | | SEQUENCE NUMBER: | |

PATIENT LAST NAME: | | | | | | | | | | | | FIRST/MIDDLE INITIALS: | |

Informed Consent Modifications or Withdrawal Form (ICMB Screen 1 of 4)

1. Purpose of completing this form: ICMB1

   C Consent for extended follow-up

   W Withdraw — Go to Item 14

   R Reinstated after withdraw — Go to Item 15

   O Other consent change — Go to Item 6

2. Has participant agreed to extend follow-up past 5 years? ICMB2

   Y Yes

   N No — Go to Item 4

3. Date participant signed consent to extend follow-up: ICMB3

   | | | / | | | / | | | | |

   Month Day Year

   Go to item 6

4. Reason why participant will not extend follow-up past 5 years: ICMB4

   T Time burden

   S Side effects from study vitamins

   M Medical condition (kidney failure, etc)

   O Other

   If other, specify reason for not extending follow-up period past 5 years:

   _____

5. Did the site principal investigator talk to the participant about the importance of extending follow-up? ICMB5

   Y Yes

   N No

   Go to item 16

Informed Consent Modifications or Withdrawal Form (ICMB Screen 2 of 4)

6. Are there any restrictions on use/storage of DNA? ICM3

   Y Yes

   N No — Go to Item 8

7. Type of restriction on use/storage of DNA: ICM4

   C Use for CVD or renal research only

   F Use for FAVORIT study only

   N No use/storage of DNA

   O Other

   If other, specify details of DNA restriction:

   _____

8. Are there any restrictions on stored (archived) blood? ICM5

   Y Yes

   N No — Go to item 10

9. Type of restriction on stored (archived) blood: ICM6

   C Use for CVD or renal research only

   F Use for FAVORIT study only

   N No use/storage of archived blood

   O Other

   If other, specify details of stored blood restrictions:_____

ID_____ CO_____ Seq No_____

Informed Consent Modifications or Withdrawal Form (ICMB Screen 3 of 4)

10. Are there any restrictions on stored (archived) urine? ICM7

Y Yes

N No — Go to item 12

11. Type of restriction on stored (archived) urine: ICM8

C Use for CVD or renal research only

F Use for FAVORIT study only

N No use/storage of urine

O Other

If other, specify details of stored urine restriction:_____

12. Has permission been granted to access medical records? ICM9

Y Yes, full access

N No access

P Partial access

If partial, specify details:

_____

13. Has permission been granted to contact informants? ICM10

Y Yes, full contact

N No contact

L Limited contact

If limited, specify details:_____

Go to item 16

Informed Consent Modifications or Withdrawal Form (ICMB Screen 4 of 4)

14. Date of withdrawal request: ICM12

		/			/				

Month Day Year

Go to item 16

15. Date reinstated: ICMB15

		/			/				

Month Day Year

16. Method of data collection: ICMB16

C Computer

P Paper

17. Date of data collection: ICMB17

		/			/				

Month Day Year

18. Initials of staff person revising consent status:

Blind_Staff_ID

See Screen_derv_niddkv1 for FINAL consent status

FAVORIT

Folic Acid for Vascular Outcome Reduction in Transplantation

INFORMED CONSENT MODIFICATIONS OR WITHDRAWAL FORM

FORM CODE: ICM VERSION: A 05/24/02

ID NUMBER: | | | | | | | | CONTACT OCCASION: | | SEQUENCE NUMBER: | |

PATIENT LAST NAME: | | | | | | | | | | | | FIRST/MIDDLE INITIALS: | |

Informed Consent Modifications or Withdrawal Form (ICMA Screen 1 of 3)

1. Has consent changed since originally obtained? ICMA1

   Y Yes

   N No — Go to Item 11

2. Date of change in consent: ICMA2

   | | | / | | | / | | | | |

   Month Day Year

3. Are there any restrictions on use/storage of DNA? ICM3

   Y Yes

   N No — Go to Item 5

4. Type of restriction on use/storage of DNA: ICM4

   C Use for CVD or renal research only

   F Use for FAVORIT study only

   N No use/storage of DNA

   O Other

   If Other, specify details of DNA restriction: _____

Informed Consent Modifications or Withdrawal Form (ICMA Screen 2 of 3)

5. Are there any restrictions on stored (archived) blood? ICM5

   Y Yes

   N No — Go to item 7

6. Type of restriction on stored (archived) blood: ICM6

   C Use for CVD or renal research only

   F Use for FAVORIT study only

   N No use/storage of archived blood

   O Other

   If other, specify details of stored blood restrictions:_____

7. Are there any restrictions on stored (archived) urine? ICM7

   Y Yes

   N No — Go to item 9

8. Type of restriction on stored (archived) urine: ICM8

   C Use for CVD or renal research only

   F Use for FAVORIT study only

   N No use/storage of urine

   O Other

   If other, specify details of stored urine restriction:_____

ID_____ **CO**_____ **Seq No**_____

Informed Consent Modifications or Withdrawal Form (ICMA Screen 3 of 3)

9. Has permission been granted to access medical records? ICM9

Y Yes, full access

N No access

P Partial access

If partial, specify details:_____

10. Has permission been granted to contact informants? ICM10

Y Yes, full contact

N No contact

L Limited contact

If limited, specify details:_____

11. Has the participant withdrawn from the study? ICM11

Y Yes

N No — Go to item 13

If Yes, specify details of withdrawal from the study:_____

12. Date of withdrawal request:

		/			/					ICM12
Month			Day			Year				

13. Initials of staff person revising consent status:

			Blind_Staff_ID

See Screen_derv_niddkv1 for FINAL consent status