

INFORMED CONSENT MODIFICATIONS OR WITHDRAWAL FORM

Folic Acid for Vascular Outcome Reduction in Transplantation

	Reduction in Transplantation	FORM CODE: ICM VERSION: C 8/17/09
	ID NUMBER:	CONTACT OCCASION: SEQUENCE NUMBER:
	PATIENT LAST NAME:	FIRST/MIDDLE INITIALS:
	Informed Consent Modifications of	r Withdrawal Form (ICMC Screen 1 of 7)
1.	Purpose of completing this form:	4. Reason why participant will not extend follow-up past 5 years:
	C Consent for extended follow-up	T Time burden
	W Withdraw — Go to Item 14	S Side effects from study vitamins
	R Reinstated after withdraw — Go to Item 15	M Medical condition (kidney failure, etc)
	O Other consent change — Go to Item 6	O Other
	Consent for closure and extended contact — Go to Item 16	If other, specify reason for not extending follow-up period past 5 years:
2.	Has participant agreed to extend follow-up past 5 years?	
	Y Yes	5. Did the site principal investigator talk to the participant about the importance of extending follow-up?
	N No — Go to Item 4	Y Yes
3.	Date participant signed consent to extend follow-up:	N No Go to Item 28
	/ / / ICMB3	
	Month Day Year	
	Go to item 6	
	Informed Consent Modifications of	r Withdrawal Form (ICMC Screen 2 of 7)
6.	Are there any restrictions on use/storage of DNA?	8. Are there any restrictions on stored (archived) blood?
	Y Yes	Y Yes
	N No — Go to Item 8	N No— Go to item 10
7.	Type of restriction on use/storage of DNA:	9. Type of restriction on stored (archived) blood:
	C Use for CVD or renal research only	C Use for CVD or renal research only
	F Use for FAVORIT study only	F Use for FAVORIT study only
	N No use/storage of DNA	N No use/storage of archived blood
	0 Other	O Other
	If other, specify details of DNA restriction:	If other, specify details of stored blood restrictions:

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

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

ICM7

12. Has permission been granted to
 access medical records?
 Y Yes, full access

ICM9

Y Yes

 $_{
m N}$ $_{
m No}$ — Go to item 12

N No access

N No access

P Partial access

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

ICM8

If partial, specify details:

C Use for CVD or renal research only

Use for FAVORIT study only

No use/storage of urine

O Other

Ν

If other, specify details of stored urine restriction:

13. Has permission been granted to contact informants?

ICM10

ICMC18

ICMC20

Y Yes, full contact

N No contact

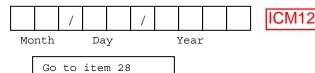
L Limited contact

If limited, specify details:

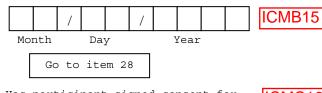
Go to item 28

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

14. Date of withdrawal request:



15. Date reinstated:



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:

Г									
1			/			/			
1			/			/			
_									
	Mo	nth		Da	17.7		Vear	_	

ICMC17

18. Type of consent:



Partial

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



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

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)? Y Yes N No—Go to Item 23 22. Contact regarding treatment arm to be made by: N Participant does not want to be contacted S Participant wants contact only by clinical site O Other If Other, specify details: ICMC21 23. Are there restrictions on contacting the participant regarding future studies in the participant regarding future studies? Y Yes N No—Go to Item 25 24. Contact regarding future studies in the participant does not want to be contacted S Participant does not want to be contacted ICMC24 S Participant wants contact only by clinical site O Other If Other, specify details: If Other, specify details:		
N No—Go to Item 23 22. Contact regarding treatment arm to be made by: N Participant does not want to be contacted S Participant wants contact only by clinical site O Other N No—Go to Item 25 24. Contact regarding future studies ICMC24 N Participant does not want to be contacted S Participant wants contact only by clinical site O Other	the participant to give them their ICMC21	
22. Contact regarding treatment arm to be made by: N Participant does not want to be contacted S Participant wants contact only by clinical site O Other 24. Contact regarding future studies ICMC24 to be made by: N Participant does not want to be contacted S Participant wants contact only by clinical site O Other	Y Yes	Y Yes
be made by: N Participant does not want to be contacted N Participant does not want to be contacted S Participant wants contact only by clinical site O Other to be made by: N Participant does not want to be contacted S Participant wants contact only by clinical site O Other	N No-Go to Item 23	N No- Go to Item 25
contacted contacted S Participant wants contact only by clinical site O Other Contacted S Participant wants contact only by clinical site O Other		
clinical site clinical site O Other O Other		
If Other, specify details:	O Other	O Other
	If Other, specify details:	If Other, specify details:

25. Participant consented to allow linkage to NDI, UNOS, USRDS, or equivalents: Y Yes P Partial N No Go to Item 28 26. Did the participant receive the consent via mail? Y Yes, trackable mail R Yes, other mail N No 27. Reason why participant did not sign consent for closure and extended contact: A After repeated attempts, unable to contact participant to determine reason for not signing consent A Medical condition/incapacitated on Participant not interested U Participant did not give a reason CMC25 27. Reason why participant did not sign consent inches in the contact participant to determine reason for not signing consent of participant inches in the contact participant of interested in the participant of interested in the consent via mail? Y Yes, trackable mail R Yes, other mail	Informed Consent Mod	lifications or W	Withdrawal Form (ICMC Screen 6 of 7)		
A After repeated attempts, unable to contact participant to determine reason for not signing consent N No D Did not attempt to contact participant If Partial, specify details: M Medical condition/incapacitated N Participant not interested U Participant did not give a reason 26. Did the participant receive the consent via mail? Y Yes, trackable mail R Yes, other mail	linkage to NDI, UNOS, USRDS, or	ICMC25	consent for closure and extended CONICZI		
N No D Did not attempt to contact participant If Partial, specify details: M Medical condition/incapacitated N Participant not interested U Participant did not give a reason 26. Did the participant receive the consent via mail? Y Yes, trackable mail R Yes, other mail			contact participant to determine		
M Medical condition/incapacitated N Participant not interested U Participant did not give a reason 26. Did the participant receive the consent via mail? Y Yes, trackable mail R Yes, other mail	N No		D Did not attempt to contact		
Go to Item 28 U Participant did not give a reason 26. Did the participant receive the consent via mail? V Yes, trackable mail R Yes, other mail U Participant did not give a reason O Other If other, specify reason for not_signing closure/extended consent:	If Partial, specify details:		M Medical condition/incapacitated		
26. Did the participant receive the consent via mail? Yes, trackable mail R Yes, other mail O Other If other, specify reason for not_signing closure/extended consent:	Go to Item 28	_			
Y Yes, trackable mail closure/extended consent: R Yes, other mail		ICMC26			
	Y Yes, trackable mail				
N No	R Yes, other mail				
	n no				

ID	CO	Seq 1	T_
		_	

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:	
Month Day Year	ICMB17
30. Initials of staff person revising consent status:	Blind_Staff_ID

See Screen_derv_niddkv1 for FINAL consent status



INFORMED CONSENT MODIFICATIONS OR WITHDRAWAL FORM

Reduction in Transplantation FOR	RM CODE: ICM VERSION: B 2/14/07
ID NUMBER: CON	SEQUENCE NUMBER:
PATIENT LAST NAME:	FIRST/MIDDLE INITIALS:
Informed Consent Modifications or Wi	thdrawal Form (ICMB Screen 1 of 4)
1. Purpose of completing this form:	4. Reason why participant will not extend follow-up past 5 years:
C Consent for extended follow-up	T Time burden
W Withdraw — Go to Item 14	S Side effects from study vitamins
R Reinstated after withdraw — Go to Item 15	M Medical condition (kidney failure, etc)
O Other consent change — Go to Item 6	O Other
2. Has participant agreed to extend ICMB2 follow-up past 5 years?	If other, specify reason for not extending follow-up period past 5 years:
Y Yes	
N No Go to Item 4 3. Date participant signed consent to extend follow-up:	5. Did the site principal investigator talk to the participant about the importance of extending follow-up? Y Yes
Marth Programme Transfer of the Control of the Cont	N No
Month Day Year Go to item 6	Go to item 16
Informed Consent Modifications or Wi	ithdrawal Form (ICMB Screen 2 of 4)
6. Are there any restrictions on use/storage of DNA?	8. Are there any restrictions on stored (archived) blood?
Y Yes	stored (archived) blood? Y Yes
N No-Go to Item 8	N No — Go to item 10
7. Type of restriction on use/storage ICM4 of DNA:	9. Type of restriction on stored ICM6
C Use for CVD or renal research only	C Use for CVD or renal research only
F Use for FAVORIT study only	F Use for FAVORIT study only
N No use/storage of DNA	N No use/storage of archived blood
O Other	O Other
If other, specify details of DNA restriction:	If other, specify details of stored blood restrictions:

CO

Seq No_____

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

	nere any restrictions on d (archived) urine?	ICM7		ermission been granted to s medical records?	ICM9
Y	Yes		Y	Yes, full access	
N	No- Go to item 12		N	No access	
			Р	Partial access	
	of restriction on stored lived) urine:	ICM8	If partia	l, specify details:	
С	Use for CVD or renal research only				
F	Use for FAVORIT study only			ermission been granted to ct informants?	ICM10
N	No use/storage of urine		Y	Yes, full contact	
0	Other		N	No contact	
	specify details of stored urine		L	Limited contact	
restricti	on:		If limite	d, specify	
			details:_		
			F	Go to item 16	

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

14. Date of withdrawal request:	16. Method of data collection: ICMB16
/ /	C Computer
Month Day Year	P Paper
Go to item 16	17. Date of data collection:
15. Date reinstated:	ICMB17
/ / / ICMB15	Month Day Year
Month Day Year	18. Initials of staff person revising consent status:
	Blind_Staff_ID

See Screen_derv_niddkv1 for FINAL consent status



INFORMED CONSENT MODIFICATIONS OR WITHDRAWAL FORM

Folic Acid for Vascular Outcome

restrictions:_____

Reduction in Transplantation FOR	RM CODE: ICM VERSION: A 05/24/02
ID NUMBER: CON	NTACT OCCASION: SEQUENCE NUMBER:
PATIENT LAST NAME:	FIRST/MIDDLE INITIALS:
Informed Consent Modifications or Wi	ithdrawal Form (ICMA Screen 1 of 3)
1. Has consent changed since originally obtained? Y Yes N No — Go to Item 11	3. Are there any restrictions on use/storage of DNA? Y Yes N No—Go to Item 5
2. Date of change in consent:	4. Type of restriction on use/storage 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 Wi	ithdrawal Form (ICMA Screen 2 of 3)
5. Are there any restrictions on stored (archived) blood?	7. Are there any restrictions on stored (archived) urine?
Y Yes	Y Yes
N No— Go to item 7	N No— Go to item 9
6. Type of restriction on stored (archived) blood:	8. Type of restriction on stored ICM8
C Use for CVD or renal research only	C Use for CVD or renal research only
F Use for FAVORIT study only	F Use for FAVORIT study only
N No use/storage of archived blood	N No use/storage of urine
O Other	O Other
If other, specify details of stored blood	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	11. Has the participant withdrawn from ICM11 the study?
Y Yes, full access		Y Yes
N No access		N No — Go to item 13
P Partial access		If Yes, specify details of withdrawal
If partial, specify		from the study:
details:		
		12. Date of withdrawal request:
10. Has permission been granted to contact informants?	ICM10	/ / / ICM12
Y Yes, full contact		Month Day Year
N No contact		13. Initials of staff person revising
L Limited contact		consent status:
If limited, specify		Blind_Staff_ID
details:	_	

See Screen_derv_niddkv1 for FINAL consent status