

INFORMED CONSENT MODIFICATIONS OR WITHDRAWAL FORM

Folic Acid for Vascular Outcome Reduction in Transplantation

	Reduction in transplaneación	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:	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 1	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	or 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
	O Other	O Other
]	of 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

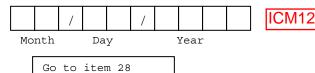
L Limited contact

If limited, specify details:

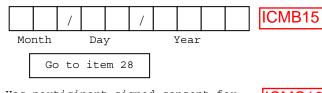
Go to item 28

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:

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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:

Informed Consent Mod	lifications or W	Withdrawal Form (ICMC Screen 6 of 7)		
25. Participant consented to allow linkage to NDI, UNOS, USRDS, or equivalents:	ICMC25	27. Reason why participant did not sign consent for closure and extended contact:		
Y Yes P Partial		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		
Go to Item 28		N Participant not interested		
		U Participant did not give a reason		
26. Did the participant receive the consent via mail?	ICMC26	0 Other		
Y Yes, trackable mail		<pre>If other, specify reason for not_signing closure/extended consent:</pre>		
R Yes, other mail				
N No				

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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	NTACT OCCASION: SEQUENCE NUMBER:
PATIENT LAST NAME:	FIRST/MIDDLE INITIALS:
Informed Consent Modifications or W	ithdrawal Form (ICMB Screen 1 of 4)
1. Purpose of completing this form: ICMB1	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 N No Go to item 16
Informed Consent Modifications or W:	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	Y Yes
$_{ m NO}$ 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 (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
O Other	O Other
If other, specify details of DNA restriction:	If other, specify details of stored blood restrictions:

ID	
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Seq No_____

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

	nere any restrictions on d (archived) urine?	ICM7		permission been granted to ss 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 lved) urine:	ICM8	If parti	al, specify details:	
С	Use for CVD or renal research only				
F	Use for FAVORIT study only		13. Has	permission been granted to act 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 limit	ed, specify	
			details:		
				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

restrictions:_____

Reduction in Transplantation FORM	I CODE: ICM VERSION: A 05/24/02		
ID NUMBER: CONT	CACT 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	3. Are there any restrictions on ICM3		
originally obtained?	use/storage or DNA?		
Y Yes	Y Yes		
N No — Go to Item 11	N No— Go to Item 5		
2. Date of change in consent:	4. Type of restriction on use/storage of DNA:		
Month Day Year	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?	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 (archived) urine:		
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
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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