

DISENROLLMENT FORM (DSEN)

CKiD Chronic Kidney Disease in Children Cohort Study

SECTION A: GENERAL INFORMATION

A1. PARTICIPANT ID: ENTER NUMBER ONLY IF LABEL IS NOT AVAILABLE

|_| - |_|_| - |_|_|_|

A2. CKiD VISIT # (next visit number child would have completed): ___ ___

A3. FORM VERSION: 0 6 / 0 1 / 0 8

A4. DATE FORM COMPLETED: ___ ___ / ___ ___ / ___ ___ ___ ___
 M M D D Y Y Y Y

A5. FORM COMPLETED BY (INITIALS) ___ ___ ___

PROMPT:
 This form should be completed for participants in which a KID ID# has been assigned AND written consent has been obtained. However, the participant *may or may not* have completed V1a.

SECTION B

B1. Disenrollment type (Circle “Yes” or “No” for each):

	<u>Yes</u>	<u>No</u>
a. CKiD Core.....	1	2
b. Carotid IMT Sub-Study.....	1	2
c. Neuroimaging Sub-Study.....	1	2
d. Additional NP testing Sub-Study.....	1	2

B2. Reason for Disenrollment (Circle ONLY one code):

Participant’s death.....	1	(Skip to B3)
Participant had kidney transplant	2	(Skip to B6)
Participant is scheduled to have kidney transplant	8	(Skip to B6)
Participant began dialysis treatment	3	(Skip to B7)
Participant is scheduled to begin dialysis treatment.....	9	(Skip to B7)
Participant’s (child’s or legal guardian’s) decision to withdraw..	4	(Skip to B8)
Site’s decision to disenroll participant.....	5	(Skip to B9)
Female participant becomes pregnant.....	6	(Skip to B10)
Other.....	7	

i. Specify: _____
 _____ **(Skip to B10)**



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B3a. Date of participant's death: ____ ____ / ____ ____ / ____ ____ ____ ____
M M D D Y Y Y Y

B3b. What was the cause of death ?

Pericarditis (incl Cardia Tamponade).....	01	Accidental, Treatment Related.....	15	Tuberculosis.....	29
Myocardial Infarction, Acute.....	02	Accidental, Not Treatment Related...	16	Aids.....	30
Cerebrovascular.....	03	Artherosclerotic Heart Disease.....	17	Other Infection.....	31
Embolism.....	04	Cardiomyopathy.....	18	Hepatitis B.....	32
Gi Hemorrhage.....	05	Cardiac Arrhythmia.....	19	Other Viral Infection.....	33
Hemorrhage (other than 03 or 05)	06	Cardiac Arrest, Cause Unknown....	20	Gastro-Intestinal Hemorrhage.	34
Pulmonary Infection.....	07	Valvular Heart Disease.....	21	Seizures.....	35
Septicemia.....	08	Pulmonary Edema Due to Exogenous Fluid.....	22	Drug Overdose (Street Drugs)	36
Viral Hepatitis.....	09	Cerebro-Vascular Accident Including Intracranial Hemorrhage.....	23	Drug Overdose (Not 14 or 36)	37
Infection (Other than 07, 08 or 09).....	10	Ischemic Brain Damage/Anoxic Enecephalopathy.....	24	Unknown.....	98
Hyperkalemia.....	11	Hemorrhage From Ruptured Vascular Aneurysm.....	25	Other Identified Cause of Death	99
Pancreatitis.....	12	Hemorrhage From Surgery.....	26		
Malignancy.....	13	Viral Infection.....	27		
Suicide.....	14	Viral Infection (Not 32 or 33)	28		

B4. Source of initial information about the cause of death (**Circle “Yes” or “No” for each**):

	<u>Yes</u>	<u>No</u>	
a. Report of family/friends.....	1	2	
b. Hospital.....	1	2	
c. Death certificate search.....	1	2	
e. Report from health care provider or social service provider.....	1	2	
f. Other source.....	1	2	(Skip to B10a)

Specify source: _____

B6. a. Scheduled or Actual Date of kidney transplant:

____ ____ / ____ ____ / ____ ____ ____ ____
M M D D Y Y Y Y

b. Name of provider and address of institution where kidney transplant will be or was performed:

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c. Were there clinical factors that prompted the scheduling or proceeding with the kidney transplant (e.g., increase in serum creatinine measurement)?

Yes..... 1 (if yes, then complete B6ci-vii)

No..... 2 (Skip to B10a)

Don't Know..... -8 (Skip to B10a)

Indicate the clinical factors that were important in deciding to proceed toward kidney transplantation from conservative management of CKD (Indicate all that may apply)

	<u>Yes</u>	<u>No</u>
i. Estimated GFR $\leq 15\text{ml}/\text{min}/1.73\text{m}^2$	1	2
ii. Rapid decline in GFR, but estimated GFR $> 15\text{ml}/\text{min}/1.73\text{m}^2$	1	2
iii. Poor Growth.....	1	2
iv. Patient/family desired pre-emptive transplantation.....	1	2
v. Need to accommodate the family/patient's school/work schedule.....	1	2
vi. Malnutrition.....	1	2
vii. Other factor, not given above.....	1	2 (Skip to B10a)

1. Please specify the other clinical factors : _____
(Skip to B10a)

B7. a. Date dialysis treatment begins or began: ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

b. Name of provider and address of institution where dialysis treatment will be or was performed:

c. Were there clinical factors that prompted the scheduling or initiating dialysis treatment (e.g., increase in serum creatinine measurement)?

Yes..... 1 (if yes, then complete B7ci-xiii)

No..... 2 (Skip to d)

Don't Know..... -8 (Skip to d)

Indicate the clinical factors that were important in deciding to initiating dialysis. (Indicate all that may apply)

	<u>Yes</u>	<u>No</u>
i. eGFR $\leq 15\text{ml}/\text{min}/1.73\text{m}^2$	1	2
ii. Rapid Decline in GFR, but eGFR > 15	1	2
iii. Poor Growth.....	1	2
iv. Urgent Need to Initiate.....	1	2
v. Hyperphosphatemia.....	1	2
vi. Hyperkalemia.....	1	2
vii. Pulmonary Edema.....	1	2
viii. Volume Overload.....	1	2
ix. Nephrotic Syndrome.....	1	2
x. Uncontrolled Hypertension.....	1	2
xi. Oligo/Anuria.....	1	2
xii. Malnutrition.....	1	2
xiii. Other factor, not given above.....	1	2

(Skip to B7d)

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1. Please specify the other clinical factors: _____

d. Did the initiation of dialysis coincide with a precipitous event/hospitalization?

- Yes..... 1
No..... 2 **(Skip to B7e)**
Don't Know..... -8 **(Skip to B7e)**

1. Briefly describe the reason for the event/hospitalization.

e. Given that the patient will begin dialysis, what are the plans for kidney transplantation?

- None at this time..... 1 **(Skip to B10a)**
Waiting for living related donor transplant..... 2 **(Skip to B10a)**
Placed on donor waiting list, no living donor available..... 3 **(Skip to B10a)**

B8. Reason for participant's decision to withdrawal:

(Circle **primary** reason for withdrawal.)

- No longer willing to follow the protocol/interested
in participating..... 1 **(Skip to B10)**
Participant/family has personal constraints..... 2 **(Skip to B10)**
Other..... 3

Specify: _____
_____ **(Skip to B10)**

B9. Specify the reason for clinical site's decision to disenroll the participant:

B10. Date of last contact (i.e., the last time someone physically saw or spoke to participant or family about CKiD)?

_ / _ / _ _ _ _
M M D D Y Y Y Y

B10. a. Did the participant request disposal of any specimen(s)? (If unable to contact, indicate "No.")

- Yes..... 1
No..... 2 **(Skip to B11)**
Don't Know..... -8 **(Skip to B11)**

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b. Which specimens did the participant want disposed?

	Yes	No
1. Serum.....	1	2
2. DNA samples.....	1	2
3. Urine.....	1	2
4. Nail Clippings.....	1	2
5. Hair Samples.....	1	2

B11. Did disenrollment occur prior to V1a study visit?

Yes..... **1 (End Here and complete PCO)**
 No..... 2

B12. Last study visit participant completed prior to disenrollment:

___ ___ (Visit #)

B13. Date of last completed study visit: ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

OBTAIN MOST RECENT HEIGHT AND LAB VALUES PRIOR TO DISENROLLMENT

B14a. Height Measurement: _____ 1=in
(round height to the nearest inch or centimeter) 2=cm

b. Date of last height measurement: ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

B15. DATE LOCAL LAB SAMPLE DRAWN: ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

B16. Renal Panel Blood Results:

a. Serum Creatinine |__| . |__| (mg/dL)

b. Urea Nitrogen (BUN) |__|__|__| (mg/dL)

**COMPLETE PARTICIPANT CLOSE-OUT FORM (PCO)
 and
 IMMEDIATELY CONTACT CCC TO COMPLETE PHONE INTERVIEW**