

Chronic Kidney Disease in Children Cohort Study (CKiD)
QUESTION BY QUESTION SPECIFICATIONS
DSEN: DISENROLLMENT FORM

This form is to be completed for each CKiD participant who has died, initiated kidney transplant therapy or dialysis treatment, expressed decision to withdraw from the study or has been deemed ineligible for the study by the clinical site. It is recommended that if a clinical site would like to disenroll a participant for the latter reason (ineligibility), the case must be discussed with the Project Director. **This form should NOT be completed for participants who are considered lost to follow-up, too ill to participate or who have moved. This form should be completed for participants for whom a KID ID# has been assigned AND written consent has been obtained. However, the participant *may or may not* have completed V1a.**

- A1. Record the participant's ID number or affix label in the space provided.
- A2. Record the visit number that corresponds to the date the participant disenrolled. If the participant died, enter the first visit number subsequent to the participant's death regardless of the date when the form is being completed. The CKiD Visit number is the next visit number the child would have completed. For example, if the participant completed a V2 study visit, then record 30 for Visit 3 which is the next visit the child would have completed if they continued participation in the study.
- A3. The form version is pre-printed. Be sure that you are using a current version and that all unused, outdated versions have been discarded. Use the form version dated 06/01/08.
- A4. Record the date in which the form is being completed – the month, day, and year.
- A5. Enter the initials of the person completing this form.

Example: K I D

SECTION B

- B1. Circle "Yes" (Code 1) or "No" (Code 2) for all applicable types of CKiD disenrollment in sub questions a through e.
- B2. Circle the **ONE CODE** that describes the reason for disenrolling the participant. If the participant died, circle (Code 1) and **skip to B3**. If the participant had or is scheduled to have a kidney transplant, circle (Code 2 or 8), **and skip to B6**. If the participant began or scheduled to begin dialysis treatment, circle (Code 3 or 9); **and skip to B7**. If the participant or the legal guardian decided to withdraw completely from the study, circle (Code 4) and **skip to B8**. This code should be circled when a participant informs CKiD staff that he/she no longer intends to participate in the study and does not wish further contact by study staff. If, however, a participant does not want to attend a particular study visit but may complete a future visit, the Missed Visit Form

should be completed instead of the Disenrollment Form. If the clinical site decides to disenroll the participant, circle (Code 5) and **skip to B9**. This code should be circled only if the participant has been deemed ineligible for the study by the clinical site. If a female participant becomes pregnant circle (Code 6) and **skip to B10**. If disenrollment occurs for some other reason, circle (Code 7), specify the reason and **skip to B10**.

- B3a. Record the date of the participant's death – the month, day, and year.
- B3b. Specify the cause of death by choosing one of the options provided. If the cause of death is unknown, circle "98" or not listed circle "99."
- B4. Specify the source of initial information about participant's death by circling "Yes" (Code 1) or "No" (Code 2) to each source in sub-answers a through f. If you select "Yes" to other source, specify the source in the provided space, otherwise **skip to B10a**.

QUESTION B5 HAS BEEN DELETED.

- B6. For sub-question "a", record the date of the participant's scheduled or actual transplant – the month, day, and year. For sub-question "b", record the name of the provider and address of the institution where the transplant was performed. For sub-question "c", indicate whether there were clinical factors that prompted the scheduling or proceeding with the kidney transplant. If there were factors, circle "Yes" (Code 1) and answer sub-questions i - vii. Otherwise, **skip to B10a**. For sub-questions i – vii, indicate the factors that were important in deciding to proceed towards kidney transplantation. If the clinical factor is not listed, provide the "other" clinical factor(s) in the space provided and **skip to B10a**.
- B7. For sub-question "a", record the date that the participant began or is scheduled to begin dialysis treatment – the month, day, and year. For sub-question "b", record the name of the provider and address of the institution where dialysis treatment was performed or will be performed. For sub-question "c", indicate whether there were clinical factors that prompted the scheduling or initiating dialysis treatment. If there were factors, circle "Yes" (Code 1) and answer sub-questions i - xiii. Otherwise **skip to sub-question d**. For sub-questions i – xiii, indicate the factors that were important in deciding to initiate dialysis. If the clinical factor is not listed, provide the "other" clinical factor(s) in the space provided. For sub-question "d", indicate whether the initiation of dialysis treatment occurred at the same time as a precipitous (quick, sudden, hasty) event/hospitalization. If "Yes" (Code 1) is circled, describe the event/hospitalization in the space provided. Otherwise, **skip to B7e**. For sub-question "e", indicate the plans for kidney transplant and **skip to B10a**.
- B8. Identify the primary reason for participant's withdrawal by circling one of three choices (Code 1 through 3) listed and **skip to B10**. If other (Code 3) is selected, specify the reason in the provided space and **skip to B10**.
- B9. Specify the reason for the clinical site's decision to disenroll the participant in the space provided.








B10. Record the date of last contact. This date is the last date that someone physically saw or spoke to the participant or family about the CKiD study. **THIS DATE SHOULD NOT BE LEFT BLANK.**

For example, if the family informed the sites on March 15, 2007 that they were no longer interested in participating in the study, then the date should be recorded as 03/15/2007.

If the child's last visit was on April 4, 2006, the last time the site spoke with the family was on January 3, 2007 and the site contacted the family several times in 2008 but calls were unanswered, the date to record would be 01/03/2007, which corresponds to the last time that someone spoke to the family/participant.

If the child's last study visit was on April 4, 2006; however, all attempts to contact the family/participant have been unsuccessful (i.e., calls have been unanswered, no one returns the call, site staff have not spoken with participant/family about CKiD during clinic visits, mailed correspondence have been unanswered or returned). For this case, the last date of contact is the last study visit date.

Please see table below for examples.

Baseline Visit	Last Visit	Date of Last Contact	Example	Status at Last Contact	Illustration
April 2005	April 2006	June 2006	Participant died in June 2006.	1	04/05 06/06 
April 2005	April 2006	June 2006	Date of transplantation was June 2006	2	04/05 06/06 
April 2005	April 2006	June 2006	Date dialysis began was June 2006	3	04/05 06/06 
April 2005	April 2006	March 2007	Participant came to last visit in April 2006 and family decided to withdraw from study on March 2007	4	04/05 03/07 
April 2005	April 2006	March 2008	Participant came to last visit in April 2006. Family contacted by phone in January 2007 and family promised to come to next visit in March 2007 but did not show up. Last phone contact with family was March 2008 and family decided they want to stop study participation (withdraw)	4	04/05 03/08 
April 2005	April 2006	January 2007	Participant came to last visit in April 2006. Family contacted by phone in January 2007 and family promised to come to next visit in March 2007 but did not show up. All subsequent attempts to contact family have been unsuccessful (no answer/no response). Site did not speak with anyone.	5	04/05 01/07 
April 2005	April 2006	April 2006	Participant came to last visit in April 2006. All attempts to contact family to schedule follow-up visits have been unsuccessful (no answer/no response.) Site did not speak with anyone.	5	04/05 04/06 

B10a. For sub-question “a”, record whether the participant requested any of the collected specimens to be disposed by circling “Yes” (Code 1), “No” (Code 2) or “Don’t Know” (Code -8). If “No” or “Don’t Know” is selected, **skip to B11**. If the family is unable to be contacted, circle “No” and **skip to B11**.

B10b. For sub-question “b”, specify which of the collected specimens the participant wants to be disposed by circling “Yes” (Code 1) or “No” (Code 2) for each of the following: Serum, DNA samples, Urine, Nail clippings, and Hair Samples.

- B11. Indicate whether disenrollment occurred prior to the V1a study visit. If “Yes” (Code 1) is circled then **END** the form and **complete the Participant Close-Out form (PCO)**. If “No” (Code 2) is circled, proceed to question B12.
- B12. Record the last study visit the participant completed prior to disenrollment.
Example: If the participant completed V1b, then record 15.
- B13. Record the date of the last completed visit – the month, day, and year

The next set of question are used to obtain most recent height and lab values prior to disenrollment.

- B14a. Record the child’s most recent height and document whether the height was taken in inches or centimeters.
- B14b. Record the date the last height measurement was taken.
- B15. Record the date of the most recent local lab sample was drawn.
- B16a-b. Record the most recent serum creatinine and urea nitrogen (BUN).

**COMPLETE PARTICIPANT CLOSE-OUR FORM (PCO) and
IMMEDIATELY CONTACT YOUR CCC TO COMPLETE A PHONE INTERVIEW.**