

## Chronic Kidney Disease in Children Cohort Study (CKiD)

### QUESTION BY QUESTION SPECIFICATIONS

#### TRS01: TRANSITIONAL FORM

#### FOR PHONE/IN-PERSON (PIP) FOLLOW-UP

This form is to be completed for each CKiD participant who has expressed decision to withdraw from the study, has been deemed ineligible for the study by the clinical site, is transitioning to adult care/aged out or pregnancy, or had/is scheduled for kidney transplant therapy or dialysis treatment.

#### SECTION A

- A1. Record the participant's ID number or affix label in the space provided.
- A2. 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 Be sure that you are using a current version and that all unused, outdated versions have been discarded.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 01/15/13a.
- A3. Record the date in which the form is being completed – the month, day, and year.
- A4. Enter the initials of the person completing this form.

Example:   K     I     D  

#### SECTION B

- B1. Circle the **ONE CODE** that describes the reason for completing the TRS01 form for the participant. If the participant had or is scheduled to have a kidney transplant, circle (Code 2 or 8), **and skip to C1**. If the participant began or is scheduled to begin dialysis treatment, circle (Code 3 or 9); **and skip to C2**. If the participant or the legal guardian decided to withdraw completely from the CKiD study, circle (Code 4) and **go to B2**. This code should be circled when a participant informs CKiD staff that he/she no longer intends to participate in the study. 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 PIP Transitional Form. If the clinical site decides to withdraw participant from regular study visits, circle (Code 5) and **skip to B3**. 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 B4**. If the participant is being transferred to adult care (i.e., aged out), circle (Code 7) and **skip to B4**.
- B2. Identify the primary reason for participant's withdrawal by circling one of five choices (Code 1 through 5) listed. If either "Participant/family has personal constraints" (Code 2), "Problem(s) with needle sticks" (Code 4) or "Family relocated outside of CKiD study area" (Code 5) is selected, **skip to B4**. However, if "No longer willing to follow the protocol/interested in participating" (Code 1) is selected, provide a more specific reason in **sub question i** and **skip to B4**. Also if "Other" (Code 3) is selected, specify the reason in the sub question i and **skip to B4**.

- B3. Identify the primary reason for the clinical site's decision to disenroll the participant by circling one of the choices (Code 1 through 3) listed. If "Other" (Code 4) is selected, specify the reason in the in sub question i.
- B4. 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 

## SECTION C

**Section C should be completed for participants who have had or are scheduled to have a transplant or dialysis treatment.**

- C1. 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 D1a**. 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 D1a**.
- C2. 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 C2e**. For sub-question “e”, indicate the plans for kidney transplant and **skip to D1a**.

## SECTION D: REPOSITORY SAMPLES

- D1. 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 D2a**. If the family is unable to be contacted, circle “No” and **skip to D2a**.
- 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.

**The next set of questions are used to obtain most recent height and lab values prior to Renal Replacement Therapy (RRT).**

- D2a. Record the child’s most recent height and document whether the height was taken in inches or centimeters.
- D2b. Record the date the last height measurement was taken.
- D3. Record the date of the most recent local lab sample was drawn.
- D4a-b. Record the most recent serum creatinine and urea nitrogen (BUN).

D5. Record the last CKiD study visit the participant completed.

**SECTION E: PARTICIPATION IN PIP PROTOCOL**

- E1a. For sub-question a, record whether the participant/family gave consent for participation in the Phone/In-Person Follow-Up Protocol by circling “Yes” (Code 1) or “No” (Code 2). If “No” is selected, **skip to E1b**. If “yes” is selected then **go to sub-question E1ai** and filling out the date of consent. After completing the date of consent, **END FORM, complete the “Child Enrolled in Phone Follow-up” on the CKiD website’s Coordinator’s Corner and download the Phone/In-Person Follow-up forms (PFU01 and PFU02) located on the CKiD website’s main page.**
- E1b. For sub-question b, record whether the participant/family has been contacted to participate in the Phone/In-Person Follow-Up Protocol by circling “Yes” (Code 1) or “No” (Code 2). If “No” is selected, **skip to E1d**.
- E1c. For sub-question c, indicate the reason(s) the participant/family did not consented for the Phone/In-Person Follow-up Protocol by circling “Yes” (Code 1) or “No” (Code 2) for each reason that applies. Circle “yes” or “no” for each of the following. If “yes” is selected for Other reason, then specify the reason. Otherwise, **END FORM & complete the Disenrollment Form (DSEN) for the participant.**
- E1d. For sub-question d, indicate the reason(s) why the participant/family has not been contacted to participate in the Phone/In-Person Follow-Up Protocol by circling “Yes” (Code 1) or “No” (Code 2) for each reason that applies. Circle “yes” or “no” for each of the following. If “yes” is selected for Other reason, then specify the reason. Otherwise, **END FORM and complete the Disenrollment Form (DSEN) for the participant.**