Chronic Kidney Disease in Children Cohort Study (CKiD)

QUESTION BY QUESTION SPECIFICATIONS

TRS03: TRANSITIONAL FORM

Prior to completing this form, contact your Clinical Coordinating Center (CCC).

This form is to be completed when a participant:

- Changes protocol participation between Regular Visits, Post RRT Visits, and PIP (Continued Follow Up).
- Who is enrolled in Post RRT Protocol experiences a change in modality (dialysis or kidney transplant).
- Who is enrolled in PIP/ePIP Protocol has a transplant and/or initiated dialysis.
- Completes an Interim (Temporary) PIP/ePIP (due to Covid-19 or another unordinary circumstance).
- Resumes study visits after an Interim PIP/ePIP (due to Covid-19 or another unordinary circumstance), or decides to discontinue in-person study visits and complete PIP/ePIP consistently.

This form should not be completed for participants enrolled in PIP/ePIP who are withdrawing from the study. For those participants, complete the DSEN form.

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 Be sure that you are using a current version and that all unused, outdated versions have been discarded.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 03/01/21.

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 TRS02 form for the participant.

- If the participants will no longer complete regular study visits, circle (Code 1) and **skip to B1b**.
- If the participant will no longer complete post RRT study visits, circle (Code 2) and **skip to B1c**.
- If the participant enrolled in the post RRT protocol is changing renal replacement therapy modalities (dialysis or transplant), circle (Code 3), **and skip to C1**.

- If the participant is enrolled in the PIP/ePIP protocol and had a transplant or initiated dialysis, circle (Code 4) **and skip to C1.**
- Due to the COVID-19 pandemic, many institutions suspended clinical research efforts. If a site is unable to complete clinical study visits due to the COVID-19 pandemic or some other unordinary circumstance, participants can temporarily transition to PIP/ePIP follow-up. Also, participants can temporarily transition to PIP/ePIP follow-up if they have an unordinary circumstance such as pregnancy which prevents them for completing in-person study visits. In these cases where the participant is willing to complete the PIP/ePIP follow-up, circle (Code 19) and **skip to F1**. Note that during pandemic, if participant is not interested in the PIP/ePIP follow-up, this form should not be completed.
- If participant was completing temporary PIP/ePIP follow-up and is ready to return to completing regular study visits, then circle (Code 21) and **end form**.
- If participant was completing temporary PIP/ePIP follow-up and is ready to return to completing post RRT study visits, then circle (Code 22) and **go to B1a**.
- If participant was completing temporary PIP/ePIP follow-up and site/participant decides to transition participant to completing PIP/ePIP on a permanent basis instead of resuming regular follow-up visits, then circle (Code 23) **and skip to B1b**.
- If participant was completing temporary PIP/ePIP follow-up and site/participant decides to transition participant to completing PIP/ePIP on a permanent basis instead of resuming post RRT visit, then circle (Code 24) **and skip to B1c**.

B1a. During the time period when a Post-RRT participant is temporarily completing PIP/ePIP follow-up, the participant may have a change in the modality of renal replacement therapy (i.e. transplant to dialysis, or vise versa). If the participant experienced a change in modality, circle yes (Code 1) **and skip to C1.** If the participant did not have a change in modality, then circle no (Code 2) **and end the form**.

B1b. Circle the **ONE CODE** that describes the reason the participant will no longer complete regular study visits.
- If the participant had or is scheduled to have a kidney transplant, circle (Code 2 or 8), **and skip to C2**.
- If the participant began or is scheduled to begin dialysis treatment, circle (Code 3 or 9); **and skip to C3.**
- If the participant or the legal guardian/authorized representative decided to withdraw completely from the CKiD study, circle (Code 4) and **skip to B2**.
  NOTE: This code should be circled when a participant informs CKiD staff that he/she no longer intends to participate in the regular in-person 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 this 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 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**.

B1c. Circle the **ONE CODE** that describes the reason the participant will no longer complete post RRT study visits.

- If the participant or the legal guardian/authorized representative decided to withdraw completely from the CKiD study, circle (Code 4) and **go to B2**.
  NOTE: This code should be circled when a participant informs CKiD staff that he/she no longer intends to participate in the post RRT in-person 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 this Transitional Form.
- If the clinical site decides to withdraw participant from post RRT 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 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 "No longer willing to follow the protocol/interested in participating" (Code 1) is selected, **skip to sub question B2i** to provide a more specific reason, then **skip to B4**.
- 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**.
- If "Other" (Code 3) is selected, **skip to sub question B2i** to provide a more specific reason, then **skip to B4**.

B3. Identify the primary reason for the clinical site's decision to withdraw the participant from study visits by circling one of the choices (Code 1 or 2) listed. If "Other" (Code 4) is selected, specify the reason in the **in sub question B3i**, then proceed to question **B4**.

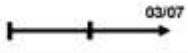
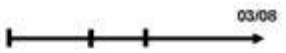
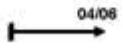
B4. Record the date of last contact. This date is the last date that someone physically saw or spoke to the participant or family about the CKiD study. **After documenting date of last contact, skip to Section E. THIS DATE SHOULD NOT BE LEFT BLANK.**

For example, if the family informed the site 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	Illustration
April 2005	April 2006	June 2006	Participant died in June 2006.	
April 2005	April 2006	June 2006	Date of transplantation was June 2006	
April 2005	April 2006	June 2006	Date dialysis began was June 2006	
April 2005	April 2006	March 2007	Participant came to last visit in April 2006 and family decided to withdraw from study on March 2007	
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 2006 and family decided they want to stop study participation (withdraw)	
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.	
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.	

SECTION C

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

C1. Document the type of event that occurred or is scheduled to occur. If a kidney transplant is scheduled or occurred, circle (code 1). If dialysis treatment is scheduled or was initiated, then circle (code 2) **and skip to C3**.

C2. Document information related to scheduled or occurred transplant.

- 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 is scheduled to occur or was performed.
- For sub-question “c”, indicate whether there were factors that prompted the scheduling or proceeding with the kidney transplant. If there were factors, circle “Yes” (Code 1) and answer **sub-questions C1ci - vii**. Otherwise, **skip to D1a**.
    - For **sub-questions C1ci – vii**, circle yes (1) to indicate the factors that were important, and circle no (2) to indicate the factors that were not 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**.

C3. Document information related to scheduled or initiated dialysis.

- For sub-question “a”, record the date the most recent regularly scheduled dialysis was started or will start – the month, day, and year.
    - For hemodialysis (i.e., cleansing the blood outside of the body), indicate the date when participant started treatments 2 or more days/week for at least 3 months.
    - For peritoneal dialysis (PD) (i.e., cleansing the blood using his/her own body tissues inside the body), indicate the date when participant started treatments 5 or more days a week for at least 3 months.
- For sub-question “b”, indicate the type of dialysis, hemodialysis (i.e., cleansing the blood outside of the body) or peritoneal dialysis (PD) (i.e., cleansing the blood using his/her own body tissues inside the body).
- For sub-question “c”, record the name of the provider and address of the institution where dialysis treatment will be, was or is performed.
- For sub-question “d”, 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 C3di - xiii**. Otherwise **skip to sub-question e**.
    - For **sub-questions C3di – xiii**, circle “Yes” (Code 1) to indicate the factors that were important and circle “No” (Code 2) to indicate the factors that were not 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 “e”, 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 and **proceed to question e.1** to describe the event/hospitalization in the space provided. Otherwise, **skip to C3f**.
- For sub-question “f”, indicate the plans for kidney transplant and **skip to D1a**.

SECTION D: PARTICIPATION IN POST-RRT PROTOCOL

D1a. Indicate whether the participant had ever completed a post-RRT study visit. If “no”, **skip to D2a**. If yes, document the last post-RRT visit number that the participant completed and then **end form**.

D2. Document information related to Post-RRT consent or dissent.

- For sub-question a, record whether the participant/family gave consent for participation in the Post-RRT Protocol.
    - If written consent has been obtained circle “Yes” (Code 1) then **go to sub-question D2ai** and fill out the date of consent. After completing the date of consent**, END FORM and schedule Post-RRT study visit.**
    - If written consent has not been obtained circle “No” (Code 2) and **skip to D2b**.
    - If the family is considering participating in the post RRT protocol but written consent has not been obtained, circle (Code 3) **then END FORM**.
- For sub-question b, record whether the participant/family has been contacted to participate in the Post-RRT Protocol by circling “Yes” (Code 1) or “No” (Code 2). If “No” is selected, **skip to D2d**.

- For sub-question c, indicate the reason(s) the participant/family did not consented for the Post-RRT Protocol by circling "Yes" (Code 1) or "No" (Code 2) for **each** reason that does or does not apply. If "yes" is selected for Other reason, then specify the reason. Otherwise, **skip to D3.**
- For sub-question d, indicate the reason(s) why the participant/family has not been contacted to participate in the Post-RRT Protocol by circling "Yes" (Code 1) or "No" (Code 2) for **each** reason that does or does not apply. If "yes" is selected for Other reason, then specify the reason. Otherwise, **skip to D3**.

D3a. Indicate whether the participant is currently enrolled in the PIP/ePIP follow-up protocol. This may be the completion of interim PIPs or regular (non-interim) PIPs. If "yes", **End Form**. Otherwise, go to Section E and document the participant's most recent height and laboratory values.

SECTION E: MOST RECENT HEIGHT AND LAB VALUES

The next set of questions are used to obtain most recent height and lab values. If the participant completed a clinical visit after their last CKiD study visit, document the height and lab values obtained at the clinical visit. Otherwise, document the height and lab values obtained at the last CKiD study visit.

E1a. Record the child's most recent height and document whether the height was taken in inches or centimeters.

E1b. Record the date the last height measurement was taken.

E2. Record the date of the most recent local lab sample was drawn.

E3a-b. Record the most recent serum creatinine and urea nitrogen (BUN).

SECTION F: PARTICIPATION IN PIP PROTOCOL

F1a. For sub-question a, record whether the participant/family gave consent for participation in the Phone/In-Person Follow-Up Protocol.
- If written consent was obtained circle "Yes" (Code 1) then **go to sub-question F1ai** and document the date of consent, then **END FORM. Complete the "Child Enrolled in Phone Follow-up" on the CKiD website's Coordinator's Corner and schedule your PIP interview & chart review. The Phone/In-Person Follow-up forms (PFU01 and PFU02) are located on the CKiD website's main page for downloading.**
- During the COVID-19 pandemic, sites working remotely may not have access to consent forms. In these cases, select "Yes, but date of consent is not accessible due to COVID-19" (Code 19) and **END form**.
- If written consent was not obtained circle "No" (Code 2) and **skip to F1b**.
- If the family is considering participating in the Phone/In-Person Follow-up protocol but written consent **has not** been obtained, circle (Code 3) **then END FORM**.

F1b. 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 F1d**.

F1c. For sub-question c, indicate the reason(s) the participant/family did not consent to the Phone/In-Person Follow-up Protocol by circling “Yes” (Code 1) or “No” (Code 2) for **each** reason that does or does not apply. If “yes” is selected for Other reason, then specify the reason. Otherwise, **END FORM & complete the Disenrollment Form (DSEN) for the participant.**

F1d. 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 does or does not apply. For example, if the family does not return calls, is unable to be reached, and/or the participant has chronic psychosocial barriers (such as mental disorders or other issues leading to homelessness, depression, anxiety, substance abuse, post-traumatic stress disorder etc.) you will circle “Yes” (Code 1) for each of these reasons. If “yes” is selected for “Other” reason, then specify the reason. Otherwise, **END FORM and complete the Disenrollment Form (DSEN) for the participant**.

“Transitional Form Status” should be completed by clinical coordinating center personnel ONLY.