

COMPREHENSIVE TRANSITIONAL FORM (TRS03)

CKiD Chronic Kidney Disease in Children Cohort Study

SECTION A: GENERAL INFORMATION

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

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

A2. FORM VERSION: 0 3 / 0 1 / 2 1

A3. DATE OF THIS REPORT: / /
M M D D Y Y Y Y

A4. FORM COMPLETED BY (INITIALS)

PROMPT: CONTACT YOUR CCC PRIOR TO COMPLETING THIS FORM.

This form should 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.*

DO NOT COMPLETE THIS FORM for participants enrolled in PIP/ePIP who are withdrawing from the study, complete the DSEN form.

B1. Reason for completing the TRS03 form.

- Participant will no longer complete Regular Study Visits..... 1 **(Skip to B1b)**
Participant will no longer complete Post RRT Study Visit..... 2 **(Skip to B1c)**
Change in post RRT protocol modality (dialysis or kidney transplant)..... 3 **(Skip to C1)**
Participant enrolled in PIP/ePIP and had transplant/initiated dialysis 4 **(Skip to C1)**
Temporary transition to PIP/ePIP follow-up due to COVID-19 pandemic or another unordinary circumstance..... 19 **(Skip to F1)**
Transition from **temporary** PIP/ePIP follow-up *back* to Regular Study Visits... 21 **(End Form)**
Transition from **temporary** PIP/ePIP follow-up *back* to Post RRT Study Visits 22
Previously completed RFU visits, transition from **temporary** PIP/ePIP follow-up to permanent PIP/ePIP follow-up Protocol..... 23 **(Skip to B1b)**
Previously completed post RRT visits, transition from **temporary** PIP/ePIP follow-up to permanent PIP/ePIP follow-up Protocol..... 24 **(Skip to B1c)**

B1a. Was there a change in modality during the time-period when participant completed temporary PIP/ePIP follow-up?

- Yes..... 1 **(Skip to C1)**
No..... 2 **(End Form)**

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B1b. Reason the participant will no longer complete Regular Study Visits

- Participant had kidney transplant..... 2 **(Skip to C2)**
- Participant is **scheduled** to have kidney transplant..... 8 **(Skip to C2)**
- Participant began dialysis treatment..... 3 **(Skip to C3)**
- Participant is **scheduled** to begin dialysis treatment..... 9 **(Skip to C3)**
- Participant's (or legal authorized representative) decision to withdraw..... 4 **(Skip to B2)**
- Site's decision to withdraw participant from regular study visits..... 5 **(Skip to B3)**
- Participant became pregnant..... 6 **(Skip to B4)**
- Participant transferred to adult care (i.e., aged out)..... 7 **(Skip to B4)**

B1c. Reason the participant will no longer complete Post RRT Study Visits

- Participant's (or legal authorized representative) decision to withdraw..... 4
- Site's decision to withdraw participant from post RRT study visits..... 5 **(Skip to B3)**
- Participant became pregnant..... 6 **(Skip to B4)**
- Participant transferred to adult care (i.e., aged out)..... 7 **(Skip to B4)**

B2. Reason for participant's decision to withdrawal from the CKiD study visits:

(Circle **primary** reason for withdrawal. Choose only one response.)

- No longer willing to follow the protocol/interested in participating..... 1 **(Go to B2i and specify reason)**
- Participant/family has personal constraints..... 2 **(Skip to B4)**
- Problem(s) with needle sticks..... 4 **(Skip to B4)**
- Family relocated outside of CKiD study area..... 5 **(Skip to B4)**
- Other..... 3

B2i. Specify: _____
_____ **(Skip to B4)**

B3. Reason for clinical site's decision to withdraw the participant from the CKiD study visits:

Circle **primary** reason for site's withdrawal. (Choose only one response.)

- Family is chronic "no show"..... 1
- Family does not return calls/unable to reach..... 2
- Other..... 4

B3i. Specify: _____
_____ **(Go to B4)**

B4. Date of last contact (i.e., the last time someone physically saw or spoke to participant or family about CKiD)? _____ / _____ / _____ **(Skip to Section E)**
M M D D Y Y Y Y

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SECTION C: TRANSPLANT/DIALYSIS TREATMENT
NOTE: Complete Section C for participants who have had or are scheduled to have a transplant or dialysis treatment.

C1. What type of event occurred/scheduled?

Had / Scheduled to have Kidney Transplant..... 1

Initiated / Scheduled to initiate Dialysis..... 2 **(skip to C3)**

C2. 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:

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

Yes..... 1 **(if yes, then complete C1ci-vii)**

No..... 2 **(Skip to D1a)**

Don't Know..... -8 **(Skip to D1a)**

Indicate the 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>	<u>Don't know</u>
i. Estimated GFR \leq 15ml/min/1.73m ²	1	2	-8
ii. Rapid decline in GFR, but estimated GFR > 15ml/min/1.73m ²	1	2	-8
iii Poor Growth.....	1	2	-8
iv. Patient/family desired pre-emptive transplantation.....	1	2	-8
v. Need to accommodate the family/patient's school/work schedule	1	2	-8
vi. Malnutrition.....	1	2	-8
vii. Other factor, not given above.....	1	2 (skip to D1a)	-8 (skip to D1a)

1. Please specify the other clinical factors : _____
(Skip to D1a)

C3. a. Date Most Recent Regularly Scheduled* Dialysis was started or will start: ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

*Indicate the start date of the most recent "regularly scheduled" dialysis.
 For hemodialysis, indicate the date when participant started treatments 2 or more days/week for at least 3 months.
 For peritoneal dialysis (PD), indicate the date when participant started treatments 5 or more days a week for at least 3 months.
 If the month or day is unknown, indicate the year. Otherwise, indicate "Don't Know."*

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b. What type of dialysis did (name of participant) use most recently:

Hemodialysis..... 1
 Peritoneal Dialysis..... 2
 Don't Know..... -8

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

d. 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 C3di-xiii)
 No..... 2 (Skip to e)
 Don't Know..... -8 (Skip to e)

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

	<u>Yes</u>	<u>No</u>	<u>Don't know</u>
i. eGFR \leq 15ml/min/1.73m ²	1	2	-8
ii. Rapid Decline in GFR, but eGFR > 15.....	1	2	-8
iii. Poor Growth.....	1	2	-8
iv. Urgent Need to Initiate.....	1	2	-8
v. Hyperphosphatemia.....	1	2	-8
vi. Hyperkalemia.....	1	2	-8
vii. Pulmonary Edema.....	1	2	-8
viii. Volume Overload.....	1	2	-8
ix. Nephrotic Syndrome.....	1	2	-8
x. Uncontrolled Hypertension.....	1	2	-8
xi. Oligo/Anuria.....	1	2	-8
xii. Malnutrition.....	1	2	-8
xiii. Other factor, not given above.....	1	2 (Skip to C3e)	-8 (skip to C3e)

1. Please specify the other clinical factors: _____

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

Yes..... 1
 No..... 2 (Skip to C3f)
 Don't Know..... -8 (Skip to C3f)

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

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- f. Given that the patient will begin or is on dialysis, what are the plans for kidney transplantation?
- None at this time..... 1 **(Skip to D1)**
- Pursuing living donor transplant..... 2 **(Skip to D1)**
- Pursuing deceased donor transplant..... 3
1. What is the patient's deceased donor transplant status?
- Placed on waiting list, active status..... 1
- Placed on waiting list, inactive status..... 2
- Not currently on waiting list..... 3
- Don't know..... -8

SECTION D: PARTICIPATION IN POST-RRT PROTOCOL
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- D1. a. Has the participant ever completed a Post RRT Protocol Study Visit?
- Yes..... 1
- No..... 2 **(Skip to D2a)**
- b. Last Post RRT visit completed: _____ **(END FORM)**
- D2. a. Did the participant/family consent to the post-RRT Protocol?
- Yes..... 1 **(Go to D2ai)**
- No..... 2 **(Skip to D2b)**
- Family considering participation in post-RRT Clinical Protocol (i.e., family agreed to participate but written consent was not obtained) 3 **(END FORM)**
- D2ai. Date of consent? ____ / ____ / ____ **(END FORM and schedule Post RRT study visit)**
- M M D D Y Y Y Y
- b. Has the participant/family been contacted to participate in the post-RRT Protocol?
- Yes..... 1
- No..... 2 **(skip to D2d)**
- c. Please indicate the reason(s) the participant/family did not consent to the post-RRT Protocol. **(Circle "Yes" or "No" for EACH of the following.)**
- | | <u>Yes</u> | <u>No</u> | |
|---|------------|-----------|---------------------|
| 1. Not interested in participating..... | 1 | 2 | |
| 2. Participant/family has personal constraints..... | 1 | 2 | |
| 3. Family relocated outside of CKiD study area..... | 1 | 2 | |
| 4. Other reason..... | 1 | 2 | (Skip to D3) |
| i. Please specify reason: _____ | | | (Skip to D3) |

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d. Please indicate the reason(s) the participant/family has not been contacted to participate in the post-RRT Clinical Protocol. **(Circle "Yes" or "No" for EACH of the following.)**

- | | <u>Yes</u> | <u>No</u> | |
|--|------------|-----------|---------------------|
| 1. Family does not return calls/unable to reach..... | 1 | 2 | |
| 2. Other reason..... | 1 | 2 | (Skip to D3) |
| i..... Please specify reason: _____ | | | |
| _____ | | | |

D3. a. Is the participant currently enrolled in the PIP/ePIP follow-up protocol?

Yes..... **1 (END Form)**

No..... **2**

SECTION E: RECORD THE MOST RECENT HEIGHT AND LAB VALUES

- E1a. 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
- E2. DATE LOCAL LAB SAMPLE DRAWN: _____
M M D D Y Y Y Y
- E3. Renal Panel Blood Results:
- a. Serum Creatinine |__| . |__| (mg/dL)
- b. Urea Nitrogen (BUN) |__| |__| |__| (mg/dL)

SECTION F: PARTICIPATION IN PHONE/IN-PERSON (PIP) FOLLOW-UP PROTOCOL

- F1. a. Did the participant/family consent to the Phone/In-Person (PIP) Follow-up Protocol?
Yes, but date of consent is not accessible due to COVID-19... **19 (END FORM)**
Yes..... **1 (Go to F1ai)**
No..... **2 (Skip to F1b)**
Family considering participation in PIP..... **3 (END FORM)**
(i.e., family agreed to participate but written consent was not obtained)
- F1ai. Date of consent? _____ **(END FORM, complete "Enrolled in Phone Follow-up" & download PIP forms from the CKiD website)**
M M D D Y Y Y Y
- b. Has the participant/family been contacted to participate in the Phone/In-Person (PIP) Follow-up Protocol?
Yes..... **1**
No..... **2 (skip to F1d)**

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c. Please indicate the reason(s) the participant/family did not consent to the Phone/In-Person Follow-up Protocol. (Circle “Yes” or “No” for EACH of the following.)

	Yes	No	
1. Not interested in participating.....	1	2	
2. Participant/family has personal constraints.....	1	2	
3. Family relocated outside of CKiD study area.	1	2	
4. Other reason.....	1	2	END FORM & complete DSEN
i. Please specify reason: _____			

Since family did not consent to PIP Follow-up Protocol, END FORM and complete DSEN.

d. Please indicate the reason(s) the participant/family has not been contacted to participate in the Phone/In-Person Follow-up Protocol. (Circle “Yes” or “No” for EACH of the following.)

	Yes	No	
1. Family does not return calls/unable to reach...	1	2	
2. Decision due to participant’s chronic psychosocial barriers and/or health decline.....	1	2	
3. Other reason.....	1	2	(If no, END FORM & complete DSEN)
ii. ... Please specify reason: _____			

END FORM and complete DSEN

TO BE COMPLETED BY CLINICAL COORDINATING CENTER PERSONNEL ONLY:

Transitional Form Status:

Participant transitioned from RFU Study Visit to Post RRT Study Visit due to transplant.....	1
Participant transitioned from RFU Study Visit to Post RRT Study Visit due to dialysis.....	2
Participant transitioned from RFU Study Visit to permanent PIP/ePIP follow-up.....	3
Participant transitioned from RFU Study Visit to temporary PIP/ePIP follow-up.....	4
Participant transitioned from RFU Study Visit to disenrollment (no consent to post RRT or PIP/ePIP follow-up)	5
Participant transitioned from Post RRT Study Visit to permanent PIP/ePIP follow-up.....	6
Participant transitioned from Post RRT Study Visit to temporary PIP/ePIP follow-up.....	7
Participant transitioned from Post RRT Study Visit to disenrollment (no consent to PIP/ePIP follow-up)	8
Participant had change in Post RRT protocol modality (dialysis to kidney transplant).....	9
Participant had change in Post RRT protocol modality (kidney transplant to dialysis).....	10
Participant transitioned from PIP/ePIP follow-up to Post RRT Protocol due to transplant.....	11
Participant transitioned from PIP/ePIP follow-up to Post RRT Protocol due to dialysis.....	12
Participant in PIP/ePIP Protocol, had transplant, decline post RRT protocol, remains in PIP/ePIP.....	13
Participant in PIP/ePIP Protocol, initiated dialysis, decline post RRT protocol, remains in PIP/ePIP.....	14
Participant transitioned from temporary PIP/ePIP follow-up <i>back</i> to Regular Study Visits.....	21
Participant transitioned from temporary PIP/ePIP follow-up <i>back</i> to Post RRT Study Visits.....	22
Participant transitioned from temporary PIP/ePIP follow-up to permanent PIP/ePIP follow-up Protocol (prior to temporary PIP/ePIP follow-up participant completed RFU visits).....	23
Participant transitioned from temporary PIP/ePIP follow-up to permanent PIP/ePIP follow-up Protocol (prior to temporary PIP/ePIP follow-up participant completed post RRT visits).....	24