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)**

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

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)

	Yes	No	Don't know
i. Estimated GFR ≤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."

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)

	Yes	No	Don't know
i. eGFR ≤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.
_____
_____
_____

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

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)**

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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.)**

		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	**(Skip to D3)**

i. Please specify reason: ____
____**(Skip to D3)**

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.)**

		Yes	No	
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 ☐ 2=cm
(round height to the nearest inch or centimeter)

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)**

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 *back* to Regular Study Visits.....	21
Participant transitioned from **temporary** PIP/ePIP follow-up *back* 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