

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 is:

- **Deceased**
- **Withdrawing from Phone/In-Person (PIP) Follow-up protocol (If dialysis or kidney transplant was initiated, please complete the TRS03 form prior to DSEN form.**
- **Declining participation in the Phone/In-Person (PIP) Follow-up protocol (i.e., family or site's decision to withdraw/disenroll from the CKiD study or family refused/not invited to participate in the PIP protocol)**
- **Assigned a KID ID# AND written consent has been obtained. However, the participant *may not* have completed V1a.**

Also, the form should be completed if TRS03 form prompts the completion of the DSEN form.

- A1. Record the participant's ID number or affix label in the space provided.
- 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 Be sure that you are using a current version and that all unused, outdated versions have been discarded.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 03/01/21.
- 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:

SECTION B

- B2. Circle the **ONE CODE** that describes the reason for disenrolling the participant.
- If the participant died, circle (Code 1) and **skip to B5a.**
 - If the participant was previously enrolled in the Phone/In-Person (PIP) Follow-up protocol, and is no longer interested in participating in the PIP protocol, then circle (Code 10), **skip to B2b.** Also, if the participant was previously enrolled in PIP and the site has decided to withdraw the participant/family (i.e., non-compliant family) or participation in PIP protocol has been discontinued, also circle (Code 10) and **skip to B2b.**
 - If the participant/family was never enrolled in PIP, then circle (Code 11), **skip to B2a.**
 - If the child consented to study participation but did NOT complete V1a, then circle (Code 99), **END Form and complete PCO.**
- B2a. Record whether more recent height measurements and lab values are available. Compare the dates on the TRS03 form to determine if more recent measurement and lab values are available. If yes, **skip to C1a** and document the most recent height measurements and lab values. Otherwise, if no, **skip to D1 and complete PCO.**

- B2b. Indicate whether the decision to disenroll was the site or participant/family. If the decision is the participant/family decision, then circle (Code 1) and proceed to B3. If the decision is the site's decision, then circle (Code 2) and **skip to B4**.
- B3. Circle the **ONE CODE** that describes the reason the participant is disenrolling from the CKiD study.
- If "No longer willing to follow the protocol/interested in participating" (Code 1) is selected, **skip to sub question B3i** to provide a more specific reason, then **skip to B8**.
 - 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 B8**.
 - If "Other" (Code 3) is selected, **skip to sub question B3i** to provide a more specific reason, then **skip to B8**.
- B4. Circle the **ONE CODE** that describes the reason the site has decided to withdraw the participant from the CKiD Study
- If the participant/family is a chronic "no show" for appointments or does not return calls/unable to reach, then circle (Code 1 or 2), **and skip to B8**.
 - If 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.) and/or health decline issues that make them unable to complete and/or adhere to study protocol, then circle (Code 3) and **skip to B8**.
 - If "Other" (Code 4) is selected, **skip to sub question B4i** to provide a more specific reason, then **skip to B8**.
- B5a. Record the date of the participant's death – the month, day, and year.
- B5b. 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."
- B6. 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 B7a**.
- B7a. Record the last study visit the participant completed prior to disenrollment.
Example: If the participant completed V1b, then record 15.
- B7b. Record the date of the last completed visit – the month, day, and year
- B8. Record the date of the last PIP Interview – the month, day, and year
If the participant died and did not participate in PIP, then circle N/A (Code -1).

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

- C1a. Record the child's most recent height and document whether the height was taken in inches or centimeters.
- C1b. Record the date the last height measurement was taken.
- C2. Record the date of the most recent local lab sample was drawn.
- C3a-b. Record the most recent serum creatinine and urea nitrogen (BUN).

- D1. 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.**

- E1a. For sub-question "a", record whether the participant/family 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, **End Form**. If the family is unable to be contacted, circle "No" and **End Form**.
- E1b. For sub-question "b", specify which of the collected specimens the participant/family 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.

**COMPLETE PARTICIPANT CLOSE-OUR FORM (PCO)
and
IMMEDIATELY CONTACT YOUR CCC**