

Chronic Kidney Disease in Children Cohort Study (CKiD)

PFU01: PHONE/IN-PERSON FOLLOW-UP INTERVIEW QUESTION BY QUESTION SPECIFICATIONS

General Instructions:

The Phone/In-Person Follow-up Interview form (PFU01) allows the study to obtain important information on study participants who no longer attend clinical visits. The PFU01 contains questions about vital status, transplantation, and dialysis. If patient death is known, do not contact the family to do a phone/in-person interview.

1. Use the correct form version.
2. All dates should be recorded in the MM/DD/YYYY format unless otherwise noted. For dates that must be completed on the form, if the participant cannot remember the exact month (and day), probe for the season. Use “15” for the day if the specific day cannot be recorded. Probe for the season and assign the month as follows:

Summer	=	July	=	07
Fall	=	October	=	10
Winter	=	January	=	01
Spring	=	April	=	04

Interviewers should have an appropriate calendar available to aid the participant in determining dates. Record as much date information as can be obtained. If the month or day is unknown, indicate the year. Otherwise, indicate “Don’t know/not sure”.

3. For questions containing an open-ended specify box linked to the response “other,” interviewers must print responses exactly in the words of the respondent.

Follow the skip patterns as they appear on the form.

4. If a participant declines to answer a certain question, document -7 to the right of the response choice(s). For the missing data, document -9 to the right of the response choices. Also document any reasons for missing data, such as the question was accidentally skipped.

PRE-INTERVIEW QUESTIONS

5. Record the participant's I.D. number or affix label in space provided.
6. The interviewer (study coordinator) should record the PIP number (e.g., 01, 02) the participant is completing. For example, if this is the first PIP survey that the participant is completing, then document 01. If it is the second PIP survey, then document 02 and so on. If there is any confusion, the interviewer should bring this to the attention of their clinical coordinating center project director for clarification before completing the form. Note that this number must match the number recorded on the PFU02 form.

7. Record the interviewer's initials. Example: K I D
8. Record the date the form is completed - the month, day and year. Example: 03/01/2007.
9. The form version is pre-printed. Use the form version dated 03/01/14.

SECTION A: VITAL STATUS

- A1. Record the date of interview – the month, day and year. Example: **03/01/2017**.
- A2. Indicate the vital status of the participant by choosing “Alive” (Code 1), “Deceased” (Code 2), or “Unknown” (Code 3). If a patient's death is previously known, do not contact the family. If vital status is “alive”, then **skip to A5**. If vital status is “unknown” because attempts to contact the participant were unsuccessful, **skip to A4**. If the family was contacted but refused to partake in the interview, choose “Alive/Contacted but refused interview” (Code 4) and **END the interview**.

- A3. Record the date of participant's death – month, day, and year.

For sub-question “i”, 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.”

- A4. Indicate whether or not the following methods of contact were used to locate or reach the participant. **Please circle “Yes” “No” or “Don't Know” for each of the following.**

- Home number
- Work number
- Family contact
- Social contact
- Other method

If “Yes” (Code 1) is selected for “Other Method”, please specify the method used in the space provided. Otherwise, proceed to question A4i.

For sub-question “i”, record the date the first attempt was made to contact the participant.

For sub-question “ii”, record the number of times attempt was made to contact the participant.

For sub-question “iii”, record the date the last attempt was made to contact the participant.

- A5. Indicate the individual reporting vital status of the participant as participant, mother, father, relative or acquaintance. The individual identified should be the person being interviewed, or the person who provides the vital status. If a relative (other than a parent) or an acquaintance reports vital status, choose code 4 and specify the relationship between this individual and the participant. If vital status is obtained via a method not specified (e.g. seeing the participant in clinic, notice via chart record), please select “Other Method” (Code 5) and specify the method used in the space provided.

SECTION B: TRANSPLANTATION

- B1. Record whether or not the participant has ever had a kidney transplant by circling “Yes” (Code 1), “No” (Code 2) or “Don’t know” (Code -8). If participant selects “No” or “Don’t know”, **skip to B2**.

For sub-question “a”, record the number of transplants the participant has had by circling “One” (Code 1), “Two” (Code 2), “Three or more” (Code 3) or “Don’t know” (Code -8).

For sub-question “b” record if the most recent kidney transplant was from a living related donor, a living non-related donor, or a deceased donor.

For sub-question “c” record the date of the participant’s most recent transplant – the month, day, and year.

For sub-question “d”, record whether the participant’s doctor discussed how well the participant’s kidney was functioning by circling “The kidney function is good/excellent” (Code 1), “The kidney is OK but (*name of participant*) might need another transplant in the near future (in 1 year or so)” (Code 3), “The kidney is not working well and (*name of participant*) is on dialysis” (Code 2), or “Don’t know” (Code -8). If the participant indicates “The kidney function is good/excellent” or “Don’t know” and then **skip to C1**.

- B2. Record whether or not the family talked about the kidney transplant with the participant’s nephrologist or health care provider in the past year by circling “Yes” (Code 1), “No” (Code 2), or “Don’t know” (Code -8). If participant selects “No” or “Don’t know”, **skip to D1**.

- B3. Indicate whether or not the participant has discussed the following donor options. **Please circle “Yes” “No” or “Don’t Know” for each of the following.**

- Living Donor
- Transplanted Waitlist/Deceased Donor

- B4. Record whether or not the participant has been listed for a deceased donor transplant (i.e., is the participant on a transplant waiting list by circling “Yes” (Code 1), “No” (Code 2), or “Don’t know” (Code -8). If participant selects “No” or “Don’t know”, **skip to D1**.

For sub-question “a”, record the date of the participant was put on the waiting list (i.e., indicated the date the participant was activated on the waiting list).

SECTION C: TRANSPLANT-RELATED MEDICATIONS

- C1. Record whether or not the participant has taken any of the listed transplant-related medication in the past 30 days by circling “Yes” (Code 1), “No” (Code 2) or “Don’t know” (Code -8). If participant selects “No” or “Don’t know”, **skip to Section D**.

- C1a. Record whether or not the participant has taken Azathioprine (Imuran) in the past 30 days by circling “Yes” (Code 1), “No” (Code 2). If participant selects “No”, **skip to C1b**. If yes, proceed to C2 and document how many times the drug was taken by circling more than 4 times/day (Code 1), four times/day (Code 2), three times/day (Code 3), twice/day (Code 4), once/day (Code 5), every other day (Code 6), 2 times/week or 3 times/week (Code 7), less than 2-3 times/week (Code 8) or Don’t

know (-8).

- C1b. Record whether or not the participant has taken Cyclosporine (Gengraf, Neoral, Sandimmune) in the past 30 days by circling “Yes” (Code 1), “No” (Code 2). If participant selects “No”, **skip to C1c**. If yes, proceed to C2 and document how many times the drug was taken by circling more than 4 times/day (Code 1), four times/day (Code 2), three times/day (Code 3), twice/day (Code 4), once/day (Code 5), every other day (Code 6), 2 times/week or 3 times/week (Code 7), less than 2-3 times/week (Code 8) or Don’t know (-8).
- C1c. Record whether or not the participant has taken Mycophenolate mofetil (Cellcept, Myfortic) in the past 30 days by circling “Yes” (Code 1), “No” (Code 2). If participant selects “No”, **skip to C1d**. If yes, proceed to C2 and document how many times the drug was taken by circling more than 4 times/day (Code 1), four times/day (Code 2), three times/day (Code 3), twice/day (Code 4), once/day (Code 5), every other day (Code 6), 2 times/week or 3 times/week (Code 7), less than 2-3 times/week (Code 8) or Don’t know (-8).
- C1d. Record whether or not the participant has taken Prednisone, Prednisolone or Methylprednisolone in the past 30 days by circling “Yes” (Code 1), “No” (Code 2). If participant selects “No”, **skip to C1e**. If yes, proceed to C2 and document how many times the drug was taken by circling more than 4 times/day (Code 1), four times/day (Code 2), three times/day (Code 3), twice/day (Code 4), once/day (Code 5), every other day (Code 6), 2 times/week or 3 times/week (Code 7), less than 2-3 times/week (Code 8) or Don’t know (-8).
- C1e. Record whether or not the participant has taken Rapamycin in the past 30 days by circling “Yes” (Code 1), “No” (Code 2). If participant selects “No”, **skip to C1f**. If yes, proceed to C2 and document how many times the drug was taken by circling more than 4 times/day (Code 1), four times/day (Code 2), three times/day (Code 3), twice/day (Code 4), once/day (Code 5), every other day (Code 6), 2 times/week or 3 times/week (Code 7), less than 2-3 times/week (Code 8) or Don’t know (-8).
- C1f. Record whether or not the participant has taken Tacrolimus (FK506, Prograf) in the past 30 days by circling “Yes” (Code 1), “No” (Code 2). If participant selects “No”, **skip to C1g**. If yes, proceed to C2 and document how many times the drug was taken by circling more than 4 times/day (Code 1), four times/day (Code 2), three times/day (Code 3), twice/day (Code 4), once/day (Code 5), every other day (Code 6), 2 times/week or 3 times/week (Code 7), less than 2-3 times/week (Code 8) or Don’t know (-8).
- C1g. Record whether or not the participant has taken Trimethoprim-Sulfamethoxazole (Bactrim, Co-trimoxazole, Sulfatrim, Septra) in the past 30 days by circling “Yes” (Code 1), “No” (Code 2). If participant selects “No”, **skip to C1h**. If yes, proceed to C2 and document how many times the drug was taken by circling more than 4 times/day (Code 1), four times/day (Code 2), three times/day (Code 3), twice/day (Code 4), once/day (Code 5), every other day (Code 6), 2 times/week or 3 times/week (Code 7), less than 2-3 times/week (Code 8) or Don’t know (-8).
- C1h. Record whether or not the participant has taken Valcyte (Valganciclovir) in the past 30 days by circling “Yes” (Code 1), “No” (Code 2). If participant selects “No”, **skip to C1i**. If yes, proceed to C2 and document how many times the drug was taken by circling more than 4 times/day (Code 1), four times/day (Code 2), three times/day (Code 3), twice/day (Code 4), once/day (Code 5), every other day (Code 6), 2 times/week or 3 times/week (Code 7), less than 2-3 times/week (Code 8) or Don’t

know (-8).

- C1i. Record whether or not the participant has taken any other transplant related medication in the past 30 days by circling “Yes” (Code 1), “No” (Code 2). For sub-question C1i1, specify the name of the drug in the space provided. If participant selects “No”, **skip to D1**. If yes, proceed to C2 and document how many times the drug was taken by circling more than 4 times/day (Code 1), four times/day (Code 2), three times/day (Code 3), twice/day (Code 4), once/day (Code 5), every other day (Code 6), 2 times/week or 3 times/week (Code 7), less than 2-3 times/week (Code 8) or Don’t know (-8).

SECTION D: DIALYSIS

- D1. Record whether or not the participant has ever been on dialysis by circling “Yes” (Code 1), “No” (Code 2), or “Don’t know” (Code -8). If participant selects “No” or “Don’t know”, **skip to D2**.

For sub-question “a”, record what type of dialysis the participant used most recently by circling “Hemodialysis (cleansing the blood outside of the body)” (Code 1), “Peritoneal Dialysis (cleansing the blood using his/her own body tissues inside the body)” (Code 2) or “Don’t know” (Code -8).

For sub-question “b”, record the date of the most recent “regular” dialysis started. For hemodialysis, indicate the date when the participant started 3 or more sessions/week. For peritoneal dialysis (PD), indicate the date when the participant started nightly dialysis.

For sub-question “c”, record whether the participant is currently receiving regular dialysis therapy by circling “Yes” (Code 1), “No” (Code 2) or “Don’t know” (Code -8). If participant selects “Yes”, **skip to Section E**.

- D2. Record whether or not the family talked about dialysis with the participant’s nephrologist or health care provider in the past year by circling “Yes” (Code 1), “No” (Code 2), or “Don’t know” (Code -8). If participant selects “No” or “Don’t know”, **skip to Section E**.
- D3. Record what type of dialysis was planned by circling “Hemodialysis (cleansing the blood outside of the body)” (Code 1), “Peritoneal Dialysis (cleansing the blood using his/her own body tissues inside the body)” (Code 2), “No decision yet” (Code 9), or “Don’t know” (Code -8).

SECTION E: GENERAL INFORMATION

- E1. Record the highest grade or level of school that the participant has completed. If the participant is currently in the 12th grade, then enter “11”, or if the participant is a sophomore in college, then enter “13”. If grade is unknown, circle “Don’t Know” (Code -8). Example: 1 1 grade (this value corresponds to 12th grade).
- E2. This question is asked to determine the number of adults living in the primary household, at least half the time. Adults are defined as all persons at least 18 years or older. Record the number of persons living in the household that are at least 18 years or older. Include participant if 18 years of age.

- E3. This question is asked to obtain more details about the adults who live in the primary household at least half the time. Remember adults are all persons at least 18 years old or older. Include the participant, if applicable. Circle “Yes” (Code 1) for each relationship the respondent mentions. Circle “No” (Code 2) if the respondent does not mention that particular relationship. Circle either “Yes” (Code 1), “No” (Code 2) or “Don’t Know” (Code -8) for each response option. **PROBE:** “Any others?” until all relationships have been established and specify those relationships. If there are transient household visitors (“Sometimes his/her father shows up”), code only those people *currently* living in the primary household.
- If “Other” person lives in the household, specify in D5i. Otherwise **skip to E4.**
- E4. This question is asked to determine the number of children living in the primary household, at least half the time. Children are defined as all persons who are less than 18 years old. Record the number of persons living in the household that are less than 18 years old. Include participant if less than 18 years of age.
- E5. This question is asked to obtain more details about the children who live in the primary household at least half the time. Remember children are all persons who are less than 18 years old. Include the participant, if applicable. Circle “Yes” (Code 1) for each relationship the respondent mentions. Circle “No” (Code 2) if the respondent does not mention that particular relationship. Circle either “Yes” (Code 1), “No” (Code 2) or “Don’t Know” (Code -8) for each response option.
- If “Other” person lives in the household, specify in D5i. Otherwise **skip to E6.**
- E6. Record the current employment status of the participant by responding “Yes”, “No” or “Don’t Know” for each employment category. If not applicable or don’t know, then circle “N/A (Code -1)” or “Don’t know (Code -8), and **skip to E7.** If participant is working full-time or part-time; indicate whether they are self-employed in sub question E6i
- E7. Record if the participant has started her menses in the past year by circling “Yes” (Code 1), “No” (Code 2) or “Don’t Know” (Code -8). If “No” or “Don’t Know” is selected, skip to **E8.** If participant is male, select “Not applicable/participant is male” and skip to E8 **PROBE: Period**
- E7a. Record the age of the participant when she started her first period. If unknown, select “Don’t Know” (Code -8).
Example: 1 3 years of age
- E8. On a scale of 1 (never) to 5 (always), ask the participant to rate how often they felt fatigue beyond their control over the past 7 days.
- E9. On a scale of 1 (never) to 5 (always), ask the participant to rate how often they were too tired to think clearly over the past 7 days.
- E10. On a scale of 1 (never) to 5 (always), ask the participant to rate their energy over the past 7 days.
- E11. On a scale of 1 (as bad as it can be) to 10 (as good as it can be), ask the participant to rate their overall quality of life over the past 7 days.

- E12. Record whether or not in the past year the participant saw a healthcare provider, nephrologist or group of providers for his/her medical appointments. Circle “Yes” (Code 1), “No” (Code 2), or “Don’t Know (Code -8). All types of visits which are **NOT** associated with CKiD should be included, such as well participant visits, sick visits and ER visits. **Do not include** times when the participant was hospitalized overnight.
- If no, complete sub-question E12a and specify the reason they have not seen a healthcare provide/nephrologist. Otherwise, **skip to E13**.
- E13. Record whether or not the participant was hospitalized in the past year by circling “Yes” (Code 1), “No” (Code 2), or “Don’t know” (Code -8). **Do not include overnight stays in the emergency room**. If participant selects “No” or “Don’t know”, **skip to E14**.
- E13a. Record the number of different times the participant was hospitalized in the past year. If unknown, select “Don’t Know”.
- Example: _0_ _2_ times
- E14. Indicate whether or not the participant has had Urinary Tract Infections in the past year. If “No” or “Don’t know” is selected, **skip to E15**.
- E14a. Record the number of different times the participant had a UTI in the past year. If unknown, select “Don’t Know”.
- Example: _0_ _2_ times
- E15. The purpose of this question is to determine whether the participants are currently with or without health insurance. The participant must select “Yes” (Code 1) or “No” (Code 2). If participant responds “No”, **skip to E16b**. Ensure that the participant considers all types of insurance listed before responding.
- PROBE: “Please include both private and public insurance programs (e.g., Medicaid, SCHIP or MCHIP), dental insurance, and programs that help pay for medications.**
- If no, complete sub-question E15a and specify the reason they do not have health insurance. Otherwise, **skip to E16b**.
- E16a. Some families may not currently have insurance coverage. The purpose of this question is to determine how long it has been since the family has had ANY covered. Participant must select one of the options: “6 months or less” (Code 1), “More than 6 months, but now more than 1 yr ago”(Code 2), “More than 1 year, but no more than 3 years ago” (Code 3), “More than 3 years” (Code 4), “Never had health insurance or coverage” (Code 5), or “Don’t Know” (Code -8). For all answer options, **skip to F1**.
- E16b. The purpose of this question is to determine if the family has had a lapse in insurance coverage. Participant must select “Yes” (Code 1) or “No” (Code 2). If participant selects “No”, **skip to F1**.
- E16c. Some families may have a lapse in insurance coverage in the past year. The purpose of this question is to determine the length of time the family was uncovered. Participant must indicate the length of time the family has been uninsured and circle

months, weeks or days.

SECTION F: MEDICAL HISTORY

- F1. Record whether or not the participant has had a heart attack by circling “Yes” (Code 1), “No” (Code 2), or “Don’t know” (Code -8).
- F2. Record whether or not the participant has had a stroke by circling “Yes” (Code 1), “No” (Code 2), or “Don’t know” (Code -8).
- F3. Record whether or not the participant has had angina (heart related chest pain) by circling “Yes” (Code 1), “No” (Code 2), or “Don’t know” (Code -8).
- F4. Record whether or not the participant has had an irregular heart rhythm by circling “Yes” (Code 1), “No” (Code 2), or “Don’t know” (Code -8).

SECTION G: BLOOD PRESSURE MEDICATIONS

- G1. Record whether or not the participant has taken any blood pressure medication in the past 30 days by circling “Yes” (Code 1), “No” (Code 2), or “Don’t know” (Code -8). If participant selects “No” or “Don’t know”, **skip to H1**.
- G2. Record the number of different blood pressure medication the participant has taken the past 30 days.
Example: _0_ _2_ times
- G3. Record whether or not the participant has taken any ACE/ARB medications in the past 30 days by circling “Yes” (Code 1), “No” (Code 2), or “Don’t know” (Code -8). If participant selects “No” or “Don’t know”, **skip to H1**.
- G4. Record the number of different ACE/ARBs the participant has taken the past 30 days.
Example: _0_ _2_ times

SECTION H: TRANSITION TO ADULT CARE

- H1. Record whether or not the participant has transitioned to adult care by circling “Yes” (Code 1), “No” (Code 2), or “Don’t know” (Code -8). If participant selects “No” or “Don’t know”, **END THE FORM**.
- H2. On a scale of 1 (Poor/Hard) to 5 (Great/Easy), ask the participant to rate their overall transition from pediatric to adult care.
If the score is less than or equal to 2, complete sub-question H2a and specify the reason the participant felt the transition was poor/hard. Otherwise, **END THE FORM**.