Chronic Kidney Disease in Children

# CKiD Study Forms by Visit

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| 29 | L12 | CENTRAL LABORATORY – IRON TESTS | | | | | |
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# SYMPTOMS LIST (F01)

## Chronic Kidney Disease in Children (CKiD)

### SECTION A: GENERAL INFORMATION

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

|__|- |__|__| - |__|__|__|

A2. CKiD STUDY VISIT #: ___ ___

A3. FORM VERSION: 0 1 / 0 1 / 0 6b

A4. DATE OF VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. INDICATE PERSON COMPLETING THE FORM
Child/young adult..... 1
Parent or other adult..... 2
Both (Parent and Child/young adult) 3

A6. Is this study visit an irregular (accelerated) visit?
Yes..... 1
No..... 2

***Instructions:*** Thinking back on the ***last month***, indicate the number of days in which your child (or you, if child/young adult participant is completing the form) has felt each of the symptoms listed below. If you/your child has never felt the symptom, then enter a "0" (zero) in the space. ***Do not leave the space blank***. If you/your child enter a "1" or number greater than 1, then ***circle the number*** under the column that best describes the severity of each of the symptom that was felt. Leave "severity" blank if the symptom was not felt.

| **Symptoms** | **Number of DAYS in past month** *(Enter 0 if none.)* | **Severity** | | |
|---|---|---|---|---|
| | | **Mild** Symptoms did not interfere with usual activities | **Moderate** Symptoms interfered somewhat with usual activities | **Severe** Symptoms were so bothersome that usual activities could not be performed |
| 1. Nausea or upset stomach? | ___ ___ | 1 | 2 | 3 |
| 2. Vomiting? | ___ ___ | 1 | 2 | 3 |
| 3. Diarrhea? | ___ ___ | 1 | 2 | 3 |
| 4. Constipation? | ___ ___ | 1 | 2 | 3 |
| 5. Itching? | ___ ___ | 1 | 2 | 3 |
| 6. Numbness and tingling in hands and/or feet? | ___ ___ | 1 | 2 | 3 |
| 7. Feeling faint when standing up? | ___ ___ | 1 | 2 | 3 |
| 8. Blurred vision? | ___ ___ | 1 | 2 | 3 |
| 9. Problems urinating (urgency, frequency, burning)? | ___ ___ | 1 | 2 | 3 |
| 10. Headaches? | ___ ___ | 1 | 2 | 3 |
| 11. A bad taste in mouth? | ___ ___ | 1 | 2 | 3 |

# SYMPTOMS LIST (F01)

| Symptoms | Number of DAYS in past month *(Enter 0 if none.)* | Severity | | |
|---|---|---|---|---|
| | | **Mild** Symptoms did not interfere with usual activities | **Moderate** Symptoms interfered somewhat with usual activities | **Severe** Symptoms were so bothersome that usual activities could not be performed |
| 12. Loss of appetite? | ___ ___ | 1 | 2 | 3 |
| 13. Increased appetite? | ___ ___ | 1 | 2 | 3 |
| 14. Weight increase? | ___ ___ | 1 | 2 | 3 |
| 15. Heartburn? | ___ ___ | 1 | 2 | 3 |
| 16. Abdominal bloating or gas? | ___ ___ | 1 | 2 | 3 |
| 17. Abdominal pain? | ___ ___ | 1 | 2 | 3 |
| 18. Swelling (excess fluid)? | ___ ___ | 1 | 2 | 3 |
| 19. Hiccoughs? | ___ ___ | 1 | 2 | 3 |
| 20. Hives or another type of rash? | ___ ___ | 1 | 2 | 3 |
| 21. Easy bruising or bleeding? | ___ ___ | 1 | 2 | 3 |
| 22. Tiring easily, weakness? | ___ ___ | 1 | 2 | 3 |
| 23. Muscle cramps? (Exclude menstrual cramps) | ___ ___ | 1 | 2 | 3 |
| 24. Waking up too early in the morning? | ___ ___ | 1 | 2 | 3 |
| 25. Falling asleep during the day? | ___ ___ | 1 | 2 | 3 |
| 26. Feeling irritable? | ___ ___ | 1 | 2 | 3 |
| 27. Decreased alertness? | ___ ___ | 1 | 2 | 3 |
| 28. Leg pain? | ___ ___ | 1 | 2 | 3 |
| 29. Flank pain (kidney pain)? | ___ ___ | 1 | 2 | 3 |
| 30. Other unexpected symptoms? ***Specify:*** _____ | ___ ___ | 1 | 2 | 3 |



**TO BE COMPLETED BY CLINICAL SITE:**

**DATE:** ___ ___/ ___ ___/ ___ ___ ___ ___
M M / D D / Y Y Y Y

**INITIALS:** ___ ___ ___

**ADMINISTRATION:**
**(Circle "1", "2" or "3")**

1 = Interviewer Assisted
2 = Self-Administered
3 = Both

## SMOKING, ALCOHOL AND DRUG USE (F02)

## Chronic Kidney Disease in Children (CKiD)

### SECTION A: GENERAL INFORMATION

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

|__|- |__|__| - |__|__|__|

A2. CKiD STUDY VISIT #: 0 1 a

A3. FORM VERSION: 1 0 / 0 1 / 1 4

A4. DATE OF VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

***This form is to be completed by children, 12 years old or older, who are enrolled in CKiD.***

### INTRODUCTION TO PARTICIPANT:

Thank you for participating in this study.

This questionnaire should take about 5 to 10 minutes. Please read each question carefully. Take as much time as you need to answer each question and be as accurate as possible. As with all study information, your answers will be kept private. No one will know who filled out the questionnaire, because there is only a code number at the top, not your name. Even your parents and your doctor will not see your answers. Please answer all questions honestly. Your answers are for research purposes only and may help doctors find better ways to treat children with kidney problems. If you have trouble reading or understanding a question, please ask the nurse/coordinator for assistance and she/he will be happy to help.

Questions begin on the next page. For each question, **FILL IN THE ANSWER or CIRCLE THE NUMBER** that best matches the answer. When you have completed the form, please return it to the nurse/coordinator.

### SECTION B: SMOKING

**The following are some personal questions about your tobacco use. Please circle the number that best matches your answer.**

B1. Have you ever smoked tobacco (e.g. a whole cigarette, cigar, cigarillo or, little cigar)?

Yes..... 1

No..... 2 **(Skip to B4)**

a. How old were you when you smoked tobacco for the first time?

___ ___ years of age

B2. Do you currently smoke tobacco?

Yes..... 1 **(Skip to B3)**
No..... 2

a. How old were you when you stopped smoking?

___ ___ years of age

b. While smoking, what was the average number of cigarettes, cigars, cigarillos or little cigars you smoked per week?

___ ___ ___ number of cigarettes, cigars, cigarillos or little cigars

**(Skip to B4)**

B3. What is the average number of cigarettes, cigars, cigarillos or little cigars you smoke per week?

___ ___ ___ number of cigarettes, cigars, cigarillos or little cigars

B4. During your life, have you ever smoked tobacco or non-tobacco (e.g., shisha, an herbal material) using a hookah?

Yes..... 1

No..... 2 **(Skip to B6)**

B5. During the **past 30 days**, how many times have you smoked tobacco or non-tobacco using a hookah?

___ ___ ___ number of times smoked tobacco or non-tobacco using a hookah

**The next 2 questions ask about electronic vapor products, such as blu, NJOY, or Starbuzz. Electronic vapor products include e-cigarettes, e-cigars, e-pipes, vape pipes, vaping pens, e-hookahs, and hookah pens.**

B6. Have you ever used an electronic vapor product?

Yes..... 1
No..... 2 **(Skip to C1)**

B7. During the **past 30 days**, on how many days did you use an electronic vapor product?

___ ___ days

## SECTION C: ALCOHOL USE

**Please answer some more personal questions; these are about drinking alcohol. Remember your answers are confidential. In these questions drinking alcohol does not include a few sips of wine for religious purposes. Drinking alcohol includes drinking beer, wine, wine coolers, and liquor such as rum, gin, vodka, or whiskey. For example, drinking alcohol includes drinking one bottle/can of beer, a glass of wine or a shot of rum.**

C1. Have you ever had a drink of alcohol?

Yes..... 1
No..... 2 **(Skip to D1)**

C2. During your life, on how many occasions have you had at least one drink of alcohol?

___ ___ ___ times

C3. During the last 12 months, on how many occasions did you have at least one drink of alcohol?

___ ___ ___ times

C4. On a typical occasion during the past 12 months, how many alcoholic drinks did you have?

___ ___ ___ drinks

C5. During the **past 30 days**, on how many days did you have at least one drink of alcohol?

___ ___ days

## SECTION D: DRUG USE

**The following are personal questions about your use of "street drugs" or non-prescribed drugs to get high. These include marijuana, synthetic marijuana, inhalants, ecstasy, and prescription drugs not prescribed to you. Remember your answers will be kept private. In the questions below, examples of opioids are OxyContin, Percocet, Vicodin, Codeine; examples of stimulants are Adderall, Ritalin, or Dexedrine; and examples of sedatives are Xanax, Valium, or Ambien.**

D1. During your life, have you ever used "street drugs"?

Yes..... 1
No..... 2 **(END FORM)**

D2. During your life, how many times have you used marijuana? Marijuana is also called grass, pot, weed, or chronic.

___ ___ ___ times

D3. During the **past 30 days**, how many times have you used marijuana?

___ ___ ___ times

D4. During the **past 30 days**, how many times have you used synthetic marijuana? Synthetic marijuana is also called K2, Spice, or fake weed.

___ ___ ___ times

D5. During your life, how many times have you sniffed glue, breathed the contents of aerosol spray cans, or inhaled any paints or sprays to get high?

___ ___ ___ times

D6. During your life, how many times have you used ecstasy (also called MDMA, X, rolls, or Molly)?

___ ___ ___ times

D7. During your life, have you taken a prescription drug (such as opioids, stimulants, or sedatives) without a doctor's prescription (i.e., a drug that was not prescribed to you)?

Yes..... 1

No..... 2 **(END)**

a. How many times have you taken a prescription opioid that was not prescribed to you?

___ ___ ___ times

b. How many times have you taken a prescription stimulant or amphetamine that was not prescribed to you?

___ ___ ___ times

c. How many times have you taken a prescription sedative or benzodiazepine that was not prescribed to you?

___ ___ ___ times

**THANK YOU FOR YOUR TIME AND EFFORT.**

## FOLLOW-UP SMOKING, ALCOHOL AND DRUG USE (F12)

## Chronic Kidney Disease in Children (CKiD)

### SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: ___ ___

A3. FORM VERSION: 1 0 / 0 1 / 1 4

A4. DATE OF VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. INTERVIEWER'S INITIALS: ___ ___ ___

***This form is to be completed by children, 12 years old or older, who are enrolled in CKiD.***

### INTRODUCTION TO PARTICIPANT:

Thank you for participating in this study.

This questionnaire should take about 5 to 10 minutes. Please read each question carefully. Take as much time as you need to answer each question and be as accurate as possible. As with all study information, your answers will be kept private. No one will know who filled out the questionnaire, because there is only a code number at the top, not your name. Even your parents and your doctor will not see your answers. Please answer all questions honestly. Your answers are for research purposes only and may help doctors find better ways to treat children with kidney problems. If you have trouble reading or understanding a question, please ask the nurse/coordinator for assistance and she/he will be happy to help.

Questions begin on the next page. For each question, **FILL IN THE ANSWER or CIRCLE THE NUMBER** that best matches the answer. When you have completed the form, please return it to the nurse/coordinator.



### SECTION B: SMOKING

**The following are some personal questions about your tobacco use. Please circle the number that best matches your answer.**

B1. In the past year, have you smoked tobacco (e.g., a whole cigarette, cigar, cigarillo or little cigar)?

Yes..... 1
No..... 2 **(Skip to B4)**

B2. Do you currently smoke tobacco?

Yes..... 1 **(Skip to B3)**
No..... 2

a. How old were you when you stopped smoking?

___ ___ years of age

b. While smoking, what was the average number of cigarettes, cigars, cigarillos or little cigars you smoked per week?

___ ___ ___ number of cigarettes, cigars, cigarillos or little cigars
**(Skip to B4)**

B3. In the past year, what is the average number of cigarettes, cigars, cigarillos or little cigars you smoke per week?

___ ___ ___ number of cigarettes, cigars, cigarillos or little cigars

B4. In the past year, have you smoked tobacco or non-tobacco (e.g., shisha, an herbal material) using a hookah?

Yes..... 1
No..... 2 **(Skip to B6)**

B5. During the **past 30 days**, how many times have you smoked tobacco or non-tobacco using a hookah?

___ ___ ___ number of times smoked tobacco or non-tobacco using a hookah

**The next 2 questions ask about electronic vapor products, such as blu, NJOY, or Starbuzz. Electronic vapor products include e-cigarettes, e-cigars, e-pipes, vape pipes, vaping pens, e-hookahs, and hookah pens.**

B6. In the past year, have you used an electronic vapor product?

Yes..... 1
No..... 2 **(Skip to C1)**

B7. During the **past 30 days**, on how many days did you use an electronic vapor product?

___ ___ days

## SECTION C: ALCOHOL USE

**Please answer some more personal questions; these are about drinking alcohol. Remember your answers are confidential. In these questions drinking alcohol does not include a few sips of wine for religious purposes. Drinking alcohol includes drinking beer, wine, wine coolers, and liquor such as rum, gin, vodka, or whiskey. For example, drinking alcohol includes drinking one bottle/can of beer, a glass of wine or a shot of rum.**

C1. In the past year, have you had a drink of alcohol?

Yes..... 1
No..... 2 **(Skip to D1)**

C2. In the past year, on how many occasions have you had at least one drink of alcohol?

___ ___ ___ times

C3. In the past year, on a typical occasion, how many alcoholic drinks did you have?

___ ___ ___ drinks

C4. During the **past 30 days**, on how many days did you have at least one drink of alcohol?

___ ___ days

## SECTION D: DRUG USE

**The following are personal questions about your use of "street drugs" or non-prescribed drugs to get high. These include marijuana, synthetic marijuana, inhalants, ecstasy and prescription drugs not prescribed to you. Remember your answers will be kept private. In the questions below, examples of opioids are OxyContin, Percocet, Vicodin, Codeine; examples of stimulants are Adderall, Ritalin, or Dexedrine; and examples of sedatives are Xanax, Valium, or Ambien.**

D1. In the past year, have you used "street drugs"?

Yes..... 1
No..... 2 **(END FORM)**

D2. In the past year, how many times have you used marijuana? Marijuana is also called grass, pot, weed, or chronic.

___ ___ ___ times

D3. During the **past 30 days**, how many times have you used marijuana?

___ ___ ___ times

D4. During the **past 30 days**, how many times have you used synthetic marijuana? Synthetic marijuana is also called K2, Spice, or fake weed.

___ ___ ___ times

D5. In the past year, how many times have you sniffed glue, breathed the contents of aerosol spray cans, or inhaled any paints or sprays to get high?

___ ___ ___ times

D6. In the past year, how many times have you used ecstasy (also called MDMA, X, rolls or Molly)?

___ ___ ___ times

D7. In the past year, have you taken a prescription drug (such as opioids, stimulants, or sedatives) without a doctor's prescription (i.e., a drug that was not prescribed to you)?

Yes..... 1

No..... 2 **(END)**

a. How many times have you taken a prescription opioid that was not prescribed to you?

___ ___ ___ times

b. How many times have you taken a prescription stimulant or amphetamine that was not prescribed to you?

___ ___ ___ times

c. How many times have you taken a prescription sedative or benzodiazepine that was not prescribed to you?

___ ___ ___ times

**THANK YOU FOR YOUR TIME AND EFFORT.**

# GENERAL HISTORY (GH)

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: 0 1 a

A3. FORM VERSION: 0 3 / 0 1 / 1 8

A4. DATE OF VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. SITE COORDINATOR'S INITIALS: ___ ___ ___

A6. INDICATE PERSON COMPLETING THE FORM

| | |
|---|---|
| Child/young adult..... | 1 |
| Parent or other adult..... | 2 |
| Both (Parent and Child/young adult) | 3 |

***For each question, fill in the answer or circle the number that best matches the respondent's answer. Circle -8 for "Don't Know" responses. If a participant declines to answer a question, document -7 to the right of the response choice(s). For missing data, document -9 to the right of the response choice(s). Please document the reason for missing data (i.e., the question was accidentally skipped.)***

***Read each question and follow skip patterns as they appear on the form. Review the QxQ for detailed descriptions of questions.***

**INTRODUCTION TO PARTICIPANT:**

**Thank you for participating in this study.**

**The following pages contain questions about the participant's family background, birth history, developmental history and family medical history. Some of the questions may be difficult for you to answer and exact dates may be hard to remember. Please take as much time as you need, so I can gather information that is as accurate as possible.**

**As with all study information, your responses will be kept strictly confidential, and the responses you provide will in no way affect the participant's clinical care. The first set of questions asks about you and the participant's background. If you have trouble understanding anything, please feel free to ask for further clarification.**

## SECTION B: INFORMATION ABOUT YOU

**The following questions are about your relationship to the participant who is participating in the study.**

B1. What is your relationship to (*name of participant*)?

| | | |
|---|---|---|
| Mother..... | 1 | → **(Skip to C1 )** |
| Father..... | 2 | → **(Skip to C1 )** |
| Legal Guardian..... | 3 | → **(Skip to C1 )** |
| Self..... | 5 | → **(Skip to C1 )** |
| Other..... | 4 | |

a. If **OTHER,** specify your relationship: _____
(Such as: grandmother, stepfather, uncle, etc.)

## SECTION C: PARTICIPANT'S BACKGROUND

**The next questions are about the participant's background.**

C1. What is (*name of participant*) date of birth?

___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

C2. What is (*name of participant*) gender?

| | |
|---|---|
| Male..... | 1 |
| Female..... | 2 |

C3. Was (*name of participant*) born in the United States of America (USA)?

| | | |
|---|---|---|
| Yes..... | 1 | **(Skip to C4)** |
| No..... | 2 | |

a. Was (*name of participant*) born in Canada?

| | | |
|---|---|---|
| Yes..... | 1 | **(Skip to C4)** |
| No..... | 2 | |

b. In what country was he or she born?

_____

c. When did (*name of participant*) move to the U.S. or Canada?

___ ___ ___ ___ (Year)

Don't Know..... -8

C4. a. Is (*name of participant*) of Hispanic or Latino/a Origin?

| | | |
|---|---|---|
| Yes, Mexican-American, Chicano | 1 | |
| Yes, Puerto Rican | 2 | |
| Yes, Cuban | 3 | |
| Yes, other Hispanic/Latino/a | 4 | |
| No, not of Hispanic or Latino/a origin | 5 | **(Skip to C5)** |
| Don't Know | -8 | **(Skip to C5)** |

b. Which language does the participant speak most frequently?

| | |
|---|---|
| English | 1 |
| Spanish | 2 |
| Both (participant is bilingual) | 3 |

C5. Which of the following describe the race of (*name of participant*)? **(Circle "Yes"," No", or "Don't Know" for EACH of the following. You may select "Yes" for more than one race.)**

| | | Yes | No | Don't Know | |
|---|---|---|---|---|---|
| a. | White | 1 | 2 | -8 | |
| b. | Black / African American | 1 | 2 | -8 | |
| c. | American Indian / Alaskan Native | 1 | 2 | -8 | |
| d. | Asian | 1 | 2 | -8 | |
| e. | Native Hawaiian/Pacific Islander | 1 | 2 | -8 | |
| f. | Other | 1 | 2 | -8 | **(If No or Don't Know to "Other", skip to D1)** |

i. If **Yes** to **Other**, specify race: _____

## SECTION D: PARTICIPANT'S BIRTH

**The next questions are about the birth of the participant who is participating in the study. The following questions also ask about the participant's biological parents. Biological parents are defined as the participant's birth or blood-related father or mother.**

D1. Was (*name of participant*)'s birth weight in pound (lbs) or kilograms (kg)?

| | | |
|---|---|---|
| lbs | 1 | |
| kg | 2 | **(Skip to b)** |
| Don't Know | -8 | **(Skip to D2)** |

a. What was (*name of the participant*)'s birth weight in lbs and ounces?

___ ___ lbs ___ ___ oz **(Skip to D2)**

b. What was (*name of participant*)'s birth weight in kilograms?

___ . ___ kg

D2. What was (*name of participant*) length at birth? (Round off to the nearest inch or centimeter. If ½ or greater round up.) **(Please circle "1" for inches or "2" for centimeters.)**

___ ___ ___ 1= inches
2= cm

Don't Know ..... -8

D3. Was (*name of participant*) born in a hospital?

Yes..... 1
No..... 2
Don't Know..... -8

D4. How was (*name of participant*) delivered?

Vaginal birth (natural)..... 1
Cesarean section (c-section)..... 2
Don't Know..... -8

D5. Was (*name of participant*) born BEFORE due date?

Yes..... 1
No..... 2 **(Skip to D6)**
Don't Know..... -8 **(Skip to D6)**

a. How many weeks BEFORE due date was (*name of participant*) born?

____ ____ weeks [this number should never exceed 20 weeks]

Don't Know..... -8

b. Was (*name of participant*) considered "pre-mature" at the time of his/her birth?

Yes..... 1
No..... 2
Don't Know..... -8

D6. Was (*name of participant*) a part of a multiple birth (e.g. a twin, triplet, etc.)?

Yes..... 1
No..... 2

D7. Immediately after birth, did (*name of participant*) spend time in the intensive care unit (ICU or NICU) before being allowed to go home?

Yes..... 1
No..... 2
Don't Know..... -8

D8. Immediately after birth, did (*name of participant*) have any kidney problems?

Yes..... 1
No..... 2
Don't Know..... -8

D9. How long was (*name of participant*) birth mother in the hospital after the delivery?

___ ___ 1 = month(s) 3 = day(s)
2 = week(s) -8 = don't know

D10. How long was (*name of participant*) in the hospital after the delivery?

___ ___ 1 = month(s) 3 = day(s)
2 = week(s) -8 = don't know

D11. What was the age of (*name of participant*) biological mother when the participant was born?

___ ___ years

Don't Know..... -8

D12. Is (*name of participant*) biological mother of Hispanic or Latina Origin?

Yes, Mexican-American, Chicano..... 1
Yes, Puerto Rican..... 2
Yes, Cuban ..... 3
Yes, other Hispanic/Latina..... 4
No, not of Hispanic or Latina origin ..... 5
Don't Know..... -8

D13. Which of the following describe the race of (*name of participant*) biological mother? **(Circle "Yes", "No" or "Don't Know" for EACH of the following. You may select "Yes" for more than one race.)**

| | | Yes | No | Don't Know | |
|---|---|---|---|---|---|
| a. | White..... | 1 | 2 | -8 | |
| b. | Black / African American..... | 1 | 2 | -8 | |
| c. | American Indian / Alaskan Native..... | 1 | 2 | -8 | |
| d. | Asian..... | 1 | 2 | -8 | |
| e. | Native Hawaiian / Pacific Islander..... | 1 | 2 | -8 | |
| f. | Other..... | 1 | 2 | -8 | **(If No or Don't Know to "Other", skip to D14)** |

i. If **Yes** to **Other**, specify race: _____

D14. What was the age of (*name of participant*) biological father when the participant was born?

___ ___ years

Don't Know..... -8

D15. Is (*name of participant*) biological father of Hispanic or Latino Origin?

Yes, Mexican-American, Chicano..... 1
Yes, Puerto Rican..... 2
Yes, Cuban ..... 3
Yes, other Hispanic/Latina..... 4
No, not of Hispanic or Latina origin..... 5
Don't Know..... -8

D16. Which of the following describe the race of (*name of participant*) biological father? **(Circle "Yes", "No" or "Don't Know" for EACH of the following. You may select "Yes" for more than one race.)**

| | | Yes | No | Don't Know | |
|---|---|---|---|---|---|
| a. | White..... | 1 | 2 | -8 | |
| b. | Black / African American..... | 1 | 2 | -8 | |
| c. | American Indian / Alaskan Native..... | 1 | 2 | -8 | |
| d. | Asian..... | 1 | 2 | -8 | |
| e. | Native Hawaiian / Pacific Islander..... | 1 | 2 | -8 | |
| f. | Other..... | 1 | 2 | -8 | **(If No or Don't Know to "Other", skip to E1)** |

1. If **Yes** to **Other**, specify race: _____

## SECTION E: PARTICIPANT'S EDUCATION

**The following questions are about the participant's education. Specifically, the next question asks about the highest grade or level of school the participant has completed. For example, if the participant is currently in the 12th grade, then enter "11", or if the participant is currently in the 6th grade, then enter "5". In addition, if the participant is in the 1st grade, kindergarten or pre-school/pre-K, then enter "0" or if participant is a sophomore in college, then enter "13".**

E1. What is the **highest** grade or level of school that (*name of participant*) has COMPLETED?

___ ___Grade

Don't Know..... -8

Not Applicable/child less than 5 years old and does not attend pre-school/pre-k..... -1

E2. Does (*name of participant*) attend school (including pre-school and pre-K) outside of the home?

Yes..... 1
No..... 2 → **(Skip to F1)**

E3. During the past school year, approximately how many days has (*name of participant*) missed from school because of not feeling well?

___ ___ Days

Don't Know..... -8

**The next two questions refer to service(s) the participant is currently receiving. If this form is completed during the summer months, please refer to the service(s) the participant received during the past school year.**

E4. Does (*name of participant*) have an individualized educational plan (IEP)? (An individualized educational plan includes special education and related services designed to address specific educational needs of children with disabilities. **REFER TO QxQ FOR DETAILED DESCRIPTION.**)

Yes..... 1
No..... 2
Don't Know..... -8
Not Applicable/child less than 5 years old..... -1 → **(Skip to F1)**

E5. Does (*name of participant*) have a 504 plan (or equivalent for Canadian sites) at school? (A 504 plan is a program designed to assist students with physical or emotional disabilities or other special needs in a regular school environment. **REFER TO QxQ FOR DETAILED DESCRIPTION.**)

Yes..... 1
No..... 2
Don't Know..... -8

## SECTION F: PARTICIPANT'S FAMILY AND PRIMARY HOUSEHOLD

**The following questions are to learn more about the participant's home and with whom he or she lives.**

F1. What is the current relationship between (*name of participant*) **biological parents**?

Not married, living together..... 1
Married, living together..... 2
Married, separated..... 3
Widowed..... 4
Divorced..... 5
Never married, not living together ..... 6
Refuse to answer..... -7
Don't Know..... -8

**The following questions ask about the participant's primary household. The primary household is the parent/guardian's home in which the participant lives at least half of the time. If the participant does not live with a parent/guardian (living independently, attending college or boarding school, emancipated, etc.), then the primary household is the parent/guardian's home where the participant used to live at least half the time prior to living independently.**

F2. How many days per week does (*name of participant*) live in the parent/guardian's primary household? (For participants who do not live with a parent/guardian, indicate the number of days the participant lived in parent/guardian's home prior to living independently.)
Indicate a number between 4 and 7.

____ days

Don't Know..... -8

F3. How many people live in the primary household at least half the time?

___ ___ people

Don't Know..... -8

F4. How many adults live in the primary household at least half the time? An adult is a person at least 18 years of age. Include **all persons at least 18 years of age**, including siblings and non-relatives. Include participant if 18 years of age.

___ ___ adults

Don't Know..... -8

F5. Which of the following adults (18 years of age or older) live in the primary household at least half the time? **(Circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| a. | Birth Mother..... | 1 | 2 | -8 |
| b. | Birth Father..... | 1 | 2 | -8 |
| c. | Step Mother/ Adoptive Mother..... | 1 | 2 | -8 |
| d. | Step Father/ Adoptive Father..... | 1 | 2 | -8 |
| e. | Participant..... | 1 | 2 | -8 |
| f. | Other..... | 1 | 2 **(Skip to F6)** | -8 **(Skip to F6)** |

i. Specify: _____

F6. Do any of the people, adults or children, living in the primary household at least half the time routinely smoke cigarettes, cigars, cigarillos or little cigars?

Yes..... 1
No..... 2
Don't Know..... -8

**The following questions are about the education level of the participant's parent(s)/guardian(s) in the primary household. Remember, primary household is defined as the home in which the participant lives at least half of the time or lived prior to living independently.**

F7. What is the highest grade or level of school that (*name of participant*) MOTHER (including birth, adoptive or stepmother) in the **primary household** has COMPLETED? For example, if completed high school enter "12 years", if completed 4-year college degree enter "16 years", and if completed doctoral degree enter "20 years."

___ ___ Years

Don't Know..... -8
No Such Person..... -1

F8. What is the highest grade or level of school that (*name of participant*) FATHER (including birth, adoptive or stepfather) in the **primary household** has COMPLETED? For example, if completed high school enter "12 years", if completed 4-year college degree enter "16 years", and if completed doctoral degree enter "20 years."

___ ___ Years

Don't Know..... -8
No Such Person..... -1

**For F9: ALLOW PARENT TO CIRCLE THE NUMBER IN THE FAR RIGHT COLUMN THAT CORRESPONDS TO THEIR TOTAL INCOME.**

F9. Please estimate the total income (before taxes) of all members of the **primary household**. Include **total income from wages, business, or investments** for all members of (*name of participant*) primary household, by year, month, or week. Do **NOT** include social security, disability insurance, or other governmental assistance. **Circle** the number in the FAR RIGHT COLUMN that corresponds to the total income.

| YEAR | MONTH | WEEK | |
|---|---|---|---|
| $6,000 OR LESS..... | $500 OR LESS..... | $115 OR LESS..... | **1** |
| $6,001 TO $12,000..... | $501 TO $1,000..... | $116 TO $231 ..... | **2** |
| $12,001 TO $18,000..... | $1,001 TO $1,500..... | $232 TO $346 ..... | **3** |
| $18,001 TO $24,000..... | $1,501 TO $2,000..... | $347 TO $461 ..... | **4** |
| $24,001 TO $30,000..... | $2,001 TO $2,500..... | $462 TO $577 ..... | **5** |
| $30,001 TO $36,000..... | $2,501 TO $3,000..... | $578 TO $692 ..... | **6** |
| $36,001 TO $75,000..... | $3,001 TO $6,250..... | $693 TO $1442 ..... | **7** |
| MORE THAN $75,000..... | MORE THAN $6,250..... | MORE THAN $1442..... | **8** |
| Don't know..... | | | **-8** |

F9a. What is the current employment status of (*name of participant*)'s MOTHER (including birth, adoptive or stepmother) in the **primary household**?

| | | |
|---|---|---|
| Working full-time (35 hours or more per week)…… | 1 | |
| Working part-time (less than 35 hours per week)….. | 2 | |
| Unemployed but seeking work…… | 3 | → **Skip to F9b** |
| Unemployed not seeking work…… | 4 | → **Skip to F9b** |
| Student…… | 5 | → **Skip to F9b** |
| Retired…… | 6 | → **Skip to F9b** |
| Disability…… | 7 | → **Skip to F9b** |
| No such person in household/Not Applicable…..... | -1 | → **Skip to F9b** |
| Don't Know…… | -8 | → **Skip to F9b** |

i. Is (*name of participant*)'s MOTHER in the **primary household** self-employed?

| | |
|---|---|
| Yes…… | 1 |
| No…… | 2 |
| Don't Know…… | -8 |

F9b. What is the current employment status of (*name of participant*)'s FATHER (including birth, adoptive or stepfather) in the **primary household**?

| | | |
|---|---|---|
| Working full-time (35 hours or more per week)…… | 1 | |
| Working part-time (less than 35 hours per week)….. | 2 | |
| Unemployed but seeking work…… | 3 | → **Skip to F9c** |
| Unemployed not seeking work…… | 4 | → **Skip to F9c** |
| Student…… | 5 | → **Skip to F9c** |
| Retired…… | 6 | → **Skip to F9c** |
| Disability…… | 7 | → **Skip to F9c** |
| No such person in household/Not Applicable…..... | -1 | → **Skip to F9c** |
| Don't Know…… | -8 | → **Skip to F9c** |

i. Is (*name of participant*)'s FATHER in the **primary household** self-employed?

| | |
|---|---|
| Yes…… | 1 |
| No…… | 2 |
| Don't Know…… | -8 |

F9c. What is the current employment status of (*name of participant*)?
**(Circle "Yes", "No", "Not applicable (N/A)" or "Don't Know" for EACH of the following.)**

| | Yes | No | N/A | Don't Know |
|---|---|---|---|---|
| Working full-time (35 hours or more per week)…… | 1 | 2 | -1 | -8 |
| Working part-time (less than 35 hours per week) | 1 | 2 | -1 | -8 |
| Disability Income…… | 1 | 2 | -1 | -8 |
| Student…… | 1 | 2 | -1 | -8 |
| Unemployed but seeking work…… | 1 **(skip to F10)** | 2 | -1 **(skip to F10)** | -8 **(skip to F10)** |
| Unemployed not seeking work…… | 1 **(skip to F10)** | 2 | -1 **(skip to F10)** | -8 **(skip to F10)** |

i. Is (*name of participant*) self-employed?

Yes..... 1
No..... 2
Don't Know..... -8

F10. What is the zip code of the where the participant currently lives at least half of the time)?

___ ___ ___ ___ ___ ___
Don't Know..... -8

F11. Has the participant lived at the current zip code for more than 1 year?

Yes..... 1 **(skip to F12)**
No..... 2
Don't Know..... -8 **(Skip to Section G)**

a. Approximately how many months has the participant lived at the current zip code?

___ ___ months
Don't Know..... -8

b. What was the zip code where the participant previously lived?

___ ___ ___ ___ ___ ___
Don't Know..... -8

c. Approximately, how many years did the participant live at the previous zip code?

___ ___ . ___ years **(Skip to Section G)**
Don't Know..... -8 **(Skip to Section G)**

F12. Approximately, how many years has the participant lived at the current zip code?

___ ___ . ___ years
Don't Know..... -8

F13. Is the participant's zip code and their parents/guardians' zip code the same?

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

F14. What is the current zip code of the parent(s)/guardian(s) (i.e., the parent(s)/guardian(s) home where the participant used to live at least half the time prior to living independently)?

___ ___ ___ ___ ___ ___
Don't Know..... -8

F15. Approximately, how long have the parent(s)/guardian(s) lived at the current zip code?

___ ___ year(s) ___ ___ month(s)

Don't Know..... -8

## SECTION G: PARTICIPANT'S FAMILY HISTORY

**The health conditions and illnesses experienced by close family members can provide important information about the participant's health. The following questions ask about the medical history of the participant's biological family. The participant's biological family includes his or her birth mother, birth father, grandparents, aunts, uncles, full brothers, full sisters and first cousins. (This does not include great aunts, great uncles and great grandparents.)** ***Full brothers and full sisters are defined as siblings who have the same birth mother and birth father as the participant.***

**Some people who lost their parents at an early age, or who were adopted, may not have information on their birth family. If you are familiar with the health history of any of the members of the participant's biological or birth family, please answer the following questions about these relatives' health to the extent that you are able. If you are uncertain of the answer to any question, please select "Don't Know." If you have trouble understanding anything, please feel free to ask for further clarification.**

G1. Do you have knowledge of the health history of any members of (*name of participant*) birth family (i.e. parents, grandparents, aunts, uncles, siblings and cousins)?

Yes…… 1
No…… 2 → **(Skip to H1)**

G2. a. How many **living half** siblings does (*name of participant*) have (Half siblings are defined as brothers and sisters, who have only one parent, either mother or birth father in common. Do not include deceased siblings.)?

___ ___ living half siblings → **(If "0", skip to G3)**

Don't Know…… -8 → **(Skip to G3)**

b. Does (*name of participant*) have any **living half** siblings in the study?

Yes…… 1
No…… 2 → **(Skip to G3)**

i. How many **living half** siblings does (*name of participant*) have participating in the study?

___ ___ living half siblings

G3. a. How many **full** siblings does (*name of participant*) have? (Full siblings are defined as brothers and sisters, who have the same birth mother and birth father as the participant. Include deceased siblings.)

___ ___ full (living and deceased) siblings → **(If "0", skip to G5)**

Don't Know…… -8 → **(Skip to G5)**

b. How many **living full** siblings does (*name of participant*) have?

___ ___ full (living) siblings → **(If "0", skip to G4)**

Don't Know…… -8 → **(Skip to G4)**

c. Does (*name of participant*) have any **living full** siblings in the study?

Yes…… 1
No…… 2 → **(Skip to G4)**

i. How many **living full** siblings does (*name of participant*) have participating in the study?

___ ___ living full siblings

G4. Please provide the date of birth for EACH of (*name of participant*) full siblings (brothers & sisters).

***START GHs1***

| | Date of Birth | | Date of Birth |
|---|---|---|---|
| a. Sibling 1 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) Don't Know…… -8 | e. Sibling 5 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) Don't Know…… -8 |
| b. Sibling 2 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) Don't Know…… -8 | f. Sibling 6 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) Don't Know…… -8 |
| c. Sibling 3 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) Don't Know…… -8 | g. Sibling 7 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) Don't Know…… -8 |
| d. Sibling 4 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) Don't Know…… -8 | h. Sibling 8 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) Don't Know…… -8 |

***END GHs1***

**The next questions ask about the family members who were told they had kidney disease and the type of kidney disease they had.**

G5. a. Including living and deceased, have any of **(*name of participant*) biological family members** been told by a health care professional that they had kidney disease?

Yes..... 1
No..... 2 → **(Skip to G8)**
Don't know..... -8 → **(Skip to G8)**

**b.** Which family members? **c.** What type of kidney disease?

| | Yes | No | | Alport's Hereditary Nephritis | Polycystic Kidney Disease | Focal Segmental Glomerulosclerosis | Reflux Nephropathy (Kidney/bladder Reflux) | Other | Don't Know |
|---|---|---|---|---|---|---|---|---|---|
| 1 Mother..... | 1 | 2 | **(#2)** | 1 | 2 | 3 | 4 | 5 **(specify)** Specify: _____ | -8 |
| 2 Father..... | 1 | 2 | **(#3)** | 1 | 2 | 3 | 4 | 5 **(specify)** Specify: _____ | -8 |
| 3 Sibling (full brother or sister)..... | 1 | 2 | **(#4)** | 1 | 2 | 3 | 4 | 5 **(specify)** Specify: _____ | -8 |
| 4 Grandparent(s)... | 1 | 2 | **(#5)** | 1 | 2 | 3 | 4 | 5 **(specify)** Specify: _____ | -8 |
| 5 Aunt(s)/Uncle(s).. | 1 | 2 | **(#6)** | 1 | 2 | 3 | 4 | 5 **(specify)** Specify: _____ | -8 |
| 6 Cousin(s)..... | 1 | 2 | **(G6)** | 1 | 2 | 3 | 4 | 5 **(specify)** Specify: _____ | -8 |

**Next, the following questions ask about (*name of participant*) biological family members.**

G6. a. Including living and deceased, have any of **(*name of participant*) biological family members** been told by a health care professional that they had the SAME kidney disease as (*name of participant)*?

Yes..... 1

No..... 2 → **(Skip to G7)**

Don't know..... -8 → **(Skip to G7)**

b. Which biological family members? Yes No

**(Circle "Yes" or "No" for EACH of the following.)**

1. Mother..... 1 2
2. Father..... 1 2
3. Sibling (full brother or sister)..... 1 2
4. Grandparent(s)..... 1 2
5. Aunt(s)/Uncle(s)..... 1 2
6. Cousin(s)..... 1 2

G7. a. Including living and deceased, have any of **(*name of participant*) biological family members** had a kidney biopsy?

Yes..... 1

No..... 2 → **(Skip to G8)**

Don't know..... -8 → **(Skip to G8)**

b. Which biological family members? Yes No

**(Circle "Yes" or "No" for EACH of the following.)**

1. Mother..... 1 2
2. Father..... 1 2
3. Sibling (full brother or sister)..... 1 2
4. Grandparent(s)..... 1 2
5. Aunt(s)/Uncle(s)..... 1 2
6. Cousin(s)..... 1 2

G8. a. Including living and deceased, have any of **(*name of participant*) biological family members** been told by a health care professional (any doctor, nurse, physician assistant or nurse practitioner) that they had…

b. Which **biological family members**? (**Circle "Yes", "No", or "Don't Know" for EACH of the following**.)

1. High Blood Pressure or Hypertension

Yes..... 1
No..... 2 → **(Skip to 2)**
Don't know..... -8 → **(Skip to 2)**

| | Yes | No | Don't Know |
|---|---|---|---|
| Mother..... | 1 | 2 | -8 |
| Father..... | 1 | 2 | -8 |
| Sibling (full brother or sister)..... | 1 | 2 | -8 |
| Grandparent(s)..... | 1 | 2 | -8 |
| Aunt(s)/Uncle(s)..... | 1 | 2 | -8 |
| Cousin(s)..... | 1 | 2 | -8 |

2. High Cholesterol

Yes..... 1
No..... 2 → **(Skip to 3)**
Don't know..... -8 → **(Skip to 3)**

| | Yes | No | Don't Know |
|---|---|---|---|
| Mother..... | 1 | 2 | -8 |
| Father..... | 1 | 2 | -8 |
| Sibling (full brother or sister)..... | 1 | 2 | -8 |
| Grandparent(s)..... | 1 | 2 | -8 |
| Aunt(s)/Uncle(s)..... | 1 | 2 | -8 |
| Cousin(s)..... | 1 | 2 | -8 |

3. Diabetes (high blood sugar or sugar diabetes)

Yes..... 1
No..... 2 → **(Skip to 4)**
Don't know..... -8 → **(Skip to 4)**

| | Yes | No | Don't Know |
|---|---|---|---|
| Mother..... | 1 | 2 | -8 |
| Father..... | 1 | 2 | -8 |
| Sibling (full brother or sister)..... | 1 | 2 | -8 |
| Grandparent(s)..... | 1 | 2 | -8 |
| Aunt(s)/Uncle(s)..... | 1 | 2 | -8 |
| Cousin(s)..... | 1 | 2 | -8 |

**(Circle "Yes", "No" or "Don't Know" for EACH of the following.)**

4. Stroke before the age of 50

| | | | |
|---|---|---|---|
| Yes..... | 1 | | |
| No..... | 2 | → | **(Skip to 5)** |
| Don't know..... | -8 | → | **(Skip to 5)** |

| | Yes | No | Don't Know |
|---|---|---|---|
| Mother..... | 1 | 2 | -8 |
| Father..... | 1 | 2 | -8 |
| Sibling (full brother or sister)..... | 1 | 2 | -8 |
| Grandparent(s)..... | 1 | 2 | -8 |
| Aunt(s)/Uncle(s)..... | 1 | 2 | -8 |
| Cousin(s)..... | 1 | 2 | -8 |

5. Heart Attack before the age of 50

| | | | |
|---|---|---|---|
| Yes..... | 1 | | |
| No..... | 2 | → | **(Skip to G9)** |
| Don't know..... | -8 | → | **(Skip to G9)** |

| | Yes | No | Don't Know |
|---|---|---|---|
| Mother..... | 1 | 2 | -8 |
| Father..... | 1 | 2 | -8 |
| Sibling (full brother or sister)..... | 1 | 2 | -8 |
| Grandparent(s)..... | 1 | 2 | -8 |
| Aunt(s)/Uncle(s)..... | 1 | 2 | -8 |
| Cousin(s)..... | 1 | 2 | -8 |

**If more than one grandparent, aunt, uncle or first cousin has had dialysis, ask your site coordinator for further instructions.**

G9. a. Including living and deceased, have any of (***name of participant***) **biological family members** had **dialysis** as treatment for kidney disease?

Yes..... 1
No..... 2 → **(Skip to G10)**
Don't Know.... -8 → **(Skip to G10)**

b. Which **biological family members**? **(Circle "Yes", "No", or "Don't Know" for EACH of the following.)**

c. At what age was treatment started?

1. Mother
Yes..... 1
No..... 2 → **(skip to 2)**
Don't Know..... -8
_____ yrs
Don't Know..... -8

2. Father
Yes..... 1
No..... 2 → **(skip to 3)**
Don't Know..... -8
___ ___ yrs
Don't Know..... -8

3. Sibling (full brother or sister)
Yes..... 1
No..... 2 → **(skip to 4)**
Don't Know..... -8
___ ___ yrs
Don't Know..... -8

4.Grandparent(s)
Yes..... 1
No..... 2 → **(skip to 5)**
Don't Know..... -8
___ ___ yrs
Don't Know..... -8

5. Aunt(s)/Uncle(s)
Yes..... 1
No..... 2 → **(skip to 6)**
Don't Know..... -8
___ ___ yrs
Don't Know..... -8

6. Cousin(s)
Yes..... 1
No..... 2 → **(skip to G10)**
Don't Know..... -8
___ ___ yrs
Don't Know..... -8

**If more than one grandparent, aunt, uncle or cousin has had a kidney transplant, ask your site coordinator for further instructions.**

G10. a. Including living and deceased, have any of **(*name of participant*) biological family members** had a **kidney transplant** as treatment for kidney disease?

Yes..... 1
No..... 2 → **(Skip to G11)**
Don't Know.... -8 → **(Skip to G11)**

b. Which **biological family members**? **(Circle "Yes", "No" or "Don't Know" for EACH of the following.)**

c. At what age was transplant performed?

| | | |
|---|---|---|
| 1. Mother | | ___ ___ yrs |
| | Yes..... 1 | Don't Know..... -8 |
| | No..... 2 | → **(skip to 2)** |
| | Don't Know..... -8 | |
| 2. Father | | ___ ___ yrs |
| | Yes..... 1 | Don't Know..... -8 |
| | No..... 2 | → **(skip to 3)** |
| | Don't Know..... -8 | |
| 3. Sibling (full brother or sister) | | ___ ___ yrs |
| | Yes..... 1 | Don't Know..... -8 |
| | No..... 2 | → **(skip to 4)** |
| | Don't Know..... -8 | |
| 4.Grandparent(s) | | ___ ___ yrs |
| | Yes..... 1 | Don't Know..... -8 |
| | No..... 2 | → **(skip to 5)** |
| | Don't Know..... -8 | |
| 5. Aunt(s)/Uncle(s) | | ___ ___ yrs |
| | Yes..... 1 | Don't Know..... -8 |
| | No..... 2 | → **(skip to 6)** |
| | Don't Know..... -8 | |
| 6. Cousin(s) | | ___ ___ yrs |
| | Yes..... 1 | Don't Know..... -8 |
| | No..... 2 | → **(skip to G11)** |
| | Don't Know..... -8 | |

G11. Have any of the birth mother's pregnancies resulted in the following?
**(Circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | Yes | No | Don't Know |
|---|---|---|---|
| Stillbirth (fetus died at birth)..... | 1 | 2 | -8 |
| Miscarriage..... | 1 | 2 | -8 |

G12. What is the current height of (*name of participant*) birth mother?

___ feet ___ ___ inches

Don't Know..... -8

G13. What is the current weight of (*name of participant*) birth mother?

___ ___ ___ lbs

Don't Know..... -8

G14. Has (*name of participant*) birth mother had recurrent Urinary Tract Infections (UTI)?

Yes..... 1
No..... 2
Don't Know..... -8

G15. What is the current height of (*name of participant*) birth father?

___ feet ___ ___ inches

Don't Know..... -8

G16. What is the current weight of (*name of participant*) birth father?

___ ___ ___ lbs

Don't Know..... -8

G17. Has (*name of participant*) birth father had recurrent Urinary Tract Infections (UTI)?

Yes..... 1
No..... 2
Don't Know..... -8

G18. Have any of (*name of participant*) siblings had recurrent Urinary Tract Infections (UTI)?

Yes..... 1
No..... 2
Don't Know..... -8
N/A, participant does not have any siblings... -1

## SECTION H: PARTICIPANT'S DEVELOPMENTAL HISTORY

**The following questions are to learn more about the participant's development. It may be difficult to recall the exact age so please take as much time as you need, allowing us to gather the most accurate information.**

H1. At what age did (*name of participant*) first perform the following activities?

| | | Age | | Don't Know | Not yet achieved |
|---|---|---|---|---|---|
| a. | Turn over..... | ___ ___ | months | -8 | 99 |
| b. | Sit alone..... | ___ ___ | months | -8 | 99 |
| c. | Crawl..... | ___ ___ | months | -8 | 99 |
| d. | Stand alone..... | ___ ___ | months | -8 | 99 |
| e. | Walk alone..... | ___ ___ | months | -8 | 99 |
| f. | Walk upstairs..... | ___ ___ | months | -8 | 99 |
| g. | Walk downstairs..... | ___ ___ | months | -8 | 99 |
| h. | Show interest in or attraction to sound (i.e., showed interest in shaking keys)..... | ___ ___ | 1=months<br>2=week(s) | | 99 |
| | | | Don't know | -8 | 99 |
| i. | Understand first words..... | ___ ___ | months | -8 | 99 |
| j. | Speak first words..... | ___ ___ | months | -8 | 99 |
| k. | Speak in sentences (3 or more words)..... | ___ ___ | months | -8 | 99 |

H2. a. Is (*name of participant*) older than 5 years of age?

Yes..... 1 → **(Skip to H2c)**

No..... 2

b. Is (*name of participant*) currently breast-fed?

Yes..... 1 → **(Skip to H3)**

No..... 2

Don't Know..... -8 → **(Skip to H3)**

c. Was (*name of participant*) breast-fed?

Yes..... 1

No..... 2 → **(Skip to H3)**

Don't Know..... -8 → **(Skip to H3)**

d. How old was (*name of participant*) when he/she was weaned from breast feeding?
**(Please circle "1" for years, "2" for months, "3" for weeks or "4" for days.)**

Age ___ ___ 1 = year(s) 3 = week(s)
2 = months 4 = days
Don't Know..... -8

H3. Is (*name of participant*) currently bottle-fed?

Yes..... 1 → **(Skip to H4)**
No..... 2
Don't Know..... -8 → **(Skip to H4)**

a. Was (*name of participant*) bottle-fed?
Yes..... 1
No..... 2 → **(Skip to H4)**
Don't Know..... -8 → **(Skip to H4)**

b. How old was (*name of participant*) when he/she was weaned from bottle feeding?
**(Please circle "1" for years, "2" for months, "3" for weeks or "4" for days.)**

Age ___ ___ 1 = year(s)
2 = months
3 = week(s)
4 = days
Don't Know..... -8

**FOR QUESTION H4 – H5, PLEASE PAY CLOSE ATTENTION TO THE SKIP PATTERNS. FOLLOW EACH SKIP PATTERN CAREFULLY. IT IS IMPORTANT TO ANSWER EACH QUESTION ACCORDING TO THE SKIP PATTERN.**

H4. Does *(name of participant)* have any wetness or leakage of urine (accidents) during the day or night?

Yes..... 1
No..... 2 → **(Skip to c)**
Don't Know..... -8 → **(Skip to c)**

a. Is *(name of participant)* wet during the day?
Yes..... 1
No..... 2
Don't Know..... -8

b. Is *(name of participant)* wet during the night?
Yes..... 1
No..... 2
Don't Know..... -8

c. Does *(name of participant)* catheterize the bladder (i.e., put a tube in the bladder)?

Yes..... 1
No..... 2 → **(Skip to H5)**
Don't Know..... -8 → **(Skip to H5)**

i. Does *(name of participant)* catheterize through the urethra?

Yes..... 1
No..... 2
Don't Know..... -8

ii. Does *(name of participant)* catheterize through a stoma?

Yes..... 1
No..... 2
Don't Know..... -8

H5. Is (*name of participant*) currently toilet trained?

Yes..... 1
No..... 2 → **(Skip to H6)**
Don't Know..... -8 → **(Skip to H6)**

a. When was (*name of participant*) toilet trained?

___ ___ years

b. After toilet training, did bed-wetting occur?

Yes..... 1
No..... 2 → **(Skip to C)**
Don't Know..... -8 → **(Skip to C)**

i. Does bed-wetting still occur?

Yes..... 1 → **(Skip to iii)**
No..... 2
Don't Know..... -8 → **(Skip to C)**

ii. At what age did bed-wetting stop?
**(Please circle "1" for years or "2" for months.)**

Age ___ ___ 1 = years
2 = months
Don't Know..... -8

iii. Were medical reasons the cause of bed-wetting?

Yes..... 1
No..... 2
Don't Know..... -8

c. After toilet training, did bed-soiling occur?

Yes..... 1
No..... 2 → **(Skip to H6)**
Don't Know..... -8 → **(Skip to H6)**

i. Does bed-soiling still occur?

Yes..... 1 → **(Skip to iii)**
No..... 2
Don't Know..... -8 → **(Skip to H6)**

ii. At what age did bed-soiling stop?
**(Please circle "1" for years or "2" for months.)**
Age ___ ___ 1 = years
2 = months
Don't Know..... -8

iii. Were medical reasons the cause of bed-soiling?
Yes..... 1
No..... 2
Don't Know..... -8

H6. Is (*name of participant*) 4 years of age or older?
Yes..... 1
No..... 2 **(Skip to H9)**

H7. During (*name of participant*) first 4 years, were any problems noted in the areas listed below?
**(Circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| a. | Eating..... | 1 | 2 | -8 |
| b. | Excessive crying..... | 1 | 2 | -8 |
| c. | Failure to thrive..... | 1 | 2 | -8 |
| d. | Motor skills..... | 1 | 2 | -8 |
| e. | Separating from parents..... | 1 | 2 | -8 |
| f. | Sleeping too little..... | 1 | 2 | -8 |
| g. | Sleeping too much..... | 1 | 2 | -8 |
| h. | Temper tantrums..... | 1 | 2 | -8 |

H8. Which hand does (*name of participant*) primarily use to write?

Primarily right..... 1

Primarily left..... 2

Ambidextrous (writes equally with both left and right hands) ... 3

**If the participant is under 4 years old, please answer the next question based on whether a doctor or health care professional has told you that the participant has had any of the following problems.**

H9. Has (*name of participant*) experienced any of the following problems?
**(Circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| a. | Feeding problem..... | 1 | 2 | -8 |
| b. | Eating disorder..... | 1 | 2 | -8 |
| c. | Underweight problem..... | 1 | 2 | -8 |
| d. | Overweight problem..... | 1 | 2 | -8 |
| e. | Walking difficulty (per healthcare professional).... | 1 | 2 | -8 |
| f. | Unclear speech (per healthcare professional)..... | 1 | 2 | -8 |
| g. | Sleep problem..... | 1 | 2 | -8 |
| h. | Colic..... | 1 | 2 | -8 |

## TO BE COMPLETED BY CLINICAL SITE:

**DATE:** ___ ___/ ___ ___/ ___ ___ ___ ___ **INITIALS:** ___ ___ ___
M M / D D / Y Y Y Y

**ADMINISTRATION:** 1 = Interviewer Assisted
**(Circle "1", "2" or "3")** 2 = Self-Administered
3 = Both

# FOLLOW-UP GENERAL HISTORY (F13)

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: ___ ___

A3. FORM VERSION: 0 3 / 0 1 / 1 8

A4. DATE OF VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. SITE COORDINATOR'S INITIALS: ___ ___ ___

A6. Is this study visit an irregular (accelerated) visit? Yes..... 1
No..... 2

A7. INDICATE PERSON COMPLETING THE FORM
Child/young adult..... 1
Parent or other adult..... 2
Both (Parent and Child/young adult) 3

---

***For each question, fill in the answer or circle the number that best matches the respondent's answer. Circle -8 for "Don't Know" responses. If a participant declines to answer a question, document -7 to the right of the response choice(s). For missing data, document -9 to the right of the response choice(s). Please document the reason for missing data (i.e., the question was accidentally skipped.)***

***Read each question and follow skip patterns as they appear on the form. Review the QxQ for detailed descriptions of questions.***

### INTRODUCTION TO PARTICIPANT:

**Thank you for participating in this study.**

**The following pages contain questions about the participant's family background and family medical history since their last study visit. Some of the questions may be difficult for you to answer and exact dates may be hard to remember. Please take as much time as you need, so I can gather information that is as accurate as possible.**

**As with all study information, your responses will be kept strictly confidential, and the responses you provide will in no way affect the participant's clinical care. The first set of questions asks about you and the participant's background. If you have trouble understanding anything please feel free to ask for further clarification.**

## SECTION B: INFORMATION ABOUT YOU

**The following questions are about your relationship to the participant who is participating in the study.**

B1. What is your relationship to (*name of participant*)?

| | | |
|---|---|---|
| Mother..... | 1 | → **(Skip to C1)** |
| Father..... | 2 | → **(Skip to C1)** |
| Legal Guardian..... | 3 | → **(Skip to C1)** |
| Self..... | 5 | → **(Skip to C1)** |
| Other..... | 4 | |

a. If **OTHER,** specify your relationship: _____

(Such as: grandmother, stepfather, uncle, etc.)

## SECTION C: PARTICIPANT'S EDUCATION

**The following questions are about the participant's education. Specifically, the next question asks about the highest grade or level of school the participant has completed. For example, if the participant is currently in the 12th grade, then enter "11", or if the participant is currently in the 6th grade, then enter "5". In addition, if the participant is in the 1st grade, kindergarten or pre-school/pre-K, then enter "0" or if participant is a sophomore in college, then enter "13".**

C1. What is the **highest** grade or level of school that (*name of participant*) has COMPLETED?

___ ___Grade

Don't Know..... -8

Not Applicable/child less than 5 years old
and does not attend pre-school/pre-k..... -1

C2. Does (*name of participant*) attend school (including pre-school and pre-K) outside of the home?

| | | |
|---|---|---|
| Yes..... | 1 | |
| No..... | 2 | → **(Skip to D1)** |

C3. During the past school year, approximately how many days has (*name of participant*) missed from school because of not feeling well?

___ ___ Days

Don't Know..... -8

**The next two questions refer to service(s) the participant is currently receiving. If this form is completed during the summer months, please refer to the service(s) the participant received during the past school year.**

C4. Does (name of participant) have an individualized educational plan (IEP)? (An individualized educational plan includes special education and related services designed to address specific educational needs of children with disabilities. REFER TO QXQ FOR DETAILED DESCRIPTION.)

| | | |
|---|---|---|
| Yes | 1 | |
| No | 2 | |
| Don't Know | -8 | |
| Not Applicable/child less than 5 years old | -1 | → **(Skip to D1)** |

C5. Does (name of participant) have a 504 plan at school (or equivalent for Canadian sites)? (A 504 plan is a program designed to assist students with physical or emotional disabilities or other special needs in a regular school environment. REFER TO QXQ FOR DETAILED DESCRIPTION.)

| | |
|---|---|
| Yes | 1 |
| No | 2 |
| Don't Know | -8 |

## SECTION D: PARTICIPANT'S FAMILY AND PRIMARY HOUSEHOLD

**The following questions are to learn more about the participant's home and with whom he or she lives.**

D1. What is the current relationship between (*name of participant*) **biological parents**?

| | |
|---|---|
| Not married, living together | 1 |
| Married, living together | 2 |
| Married, separated | 3 |
| Widowed | 4 |
| Divorced | 5 |
| Never married, not living together | 6 |
| Refuse to answer | -7 |
| Don't Know | -8 |

# FOLLOW-UP GENERAL HISTORY (F13)

**The following questions ask about the participant's primary household. The primary household is the parent/guardian's home in which the participant lives at least half of the time. If the participant does not live with a parent/guardian (living independently, attending college or boarding school, emancipated, etc.), then the primary household is the parent/guardian's home where the participant used to live at least half the time prior to living independently.**

D2. How many days per week does (*name of participant*) live in the primary household?
Indicate a number between 4 and 7. (For participants who do not live with a parent/guardian, indicate the number of days the participant lived in parent/guardian's home prior to living independently.)

____ days

Don't Know..... -8

D3. How many people live in the primary household at least half the time?

___ ___ people

Don't Know..... -8

D4. How many adults live in the primary household at least half the time? An adult is a person at least 18 years of age. Include **all persons at least 18 years of age**, including siblings and non-relatives. Include participant if 18 years of age.

___ ___ adults

Don't Know..... -8

D5. Which of the following adults (18 years of age and older) live in the primary household at least half the time? Include the participant, if applicable. **(Circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | Yes | No | Don't Know |
|---|---|---|---|
| a. Birth Mother..... | 1 | 2 | -8 |
| b. Birth Father..... | 1 | 2 | -8 |
| c. Step Mother/ Adoptive Mother..... | 1 | 2 | -8 |
| d. Step Father/ Adoptive Father..... | 1 | 2 | -8 |
| e. Participant..... | 1 | 2 | -8 |
| f. Other..... | 1 | 2 **(Skip to D6)** | -8 **(Skip to D6)** |
| i. Specify: _____ | | | |

D6. Do any of the people, adults or children, living in the primary household at least half the time routinely smoke cigarettes, cigars, cigarillos or little cigars?

Yes..... 1
No..... 2
Don't Know..... -8

# FOLLOW-UP GENERAL HISTORY (F13)

**The following questions are about the education level of the participant's parent(s)/guardian(s) in the primary household. Remember, primary household is defined as the home in which the participant lives at least half of the time or lived prior to living independently.**

D7. What is the highest grade or level of school that (*name of participant*) MOTHER (including birth, adoptive or stepmother) in the **primary household** has COMPLETED? For example, if completed high school enter "12 years", if completed 4-year college degree enter "16 years", and if completed doctoral degree enter "20 years."

___ ___ Years

Don't Know..... -8
No Such Person..... -1

D8. What is the highest grade or level of school that (*name of participant*) FATHER (including birth, adoptive or stepfather) in the **primary household** has COMPLETED? For example, if completed high school enter "12 years", if completed 4-year college degree enter "16 years", and if completed doctoral degree enter "20 years."

___ ___ Years

Don't Know..... -8
No Such Person..... -1

**For D9: ALLOW RESPONDENT TO CIRCLE THE NUMBER IN THE FAR RIGHT COLUMN THAT CORRESPONDS TO THEIR TOTAL INCOME.**

D9. Please estimate the total income (before taxes) of all members of the **primary household**. Include **total income from wages, business, or investments** for all members of (*name of participant*) primary household, by year, month, or week. Do **NOT** include social security, disability insurance, or other governmental assistance. **Circle** the number in the FAR RIGHT COLUMN that corresponds to the total income.

| YEAR | MONTH | WEEK | |
|---|---|---|---|
| $6,000 OR LESS..... | $500 OR LESS..... | $115 OR LESS..... | **1** |
| $6,001 TO $12,000..... | $501 TO $1,000..... | $116 TO $231..... | **2** |
| $12,001 TO $18,000..... | $1,001 TO $1,500..... | $232 TO $346..... | **3** |
| $18,001 TO $24,000..... | $1,501 TO $2,000..... | $347 TO $461..... | **4** |
| $24,001 TO $30,000..... | $2,001 TO $2,500..... | $462 TO $577..... | **5** |
| $30,001 TO $36,000..... | $2,501 TO $3,000..... | $578 TO $692..... | **6** |
| $36,001 TO $75,000..... | $3,001 TO $6,250..... | $693 TO $1442..... | **7** |
| MORE THAN $75,000..... | MORE THAN $6,250..... | MORE THAN $1442..... | **8** |
| Don't know..... | | | **-8** |

D9a. What is the current employment status of (*name of participant*) MOTHER (including birth, adoptive or stepmother) in the **primary household**?

| | | |
|---|---|---|
| Working full-time (35 hours or more per week)…….. | 1 | |
| Working part-time (less than 35 hours per week)….. | 2 | |
| Unemployed but seeking work…….. | 3 | → **Skip to D9b** |
| Unemployed not seeking work…….. | 4 | → **Skip to D9b** |
| Student…….. | 5 | → **Skip to D9b** |
| Retired…….. | 6 | → **Skip to D9b** |
| Disability…….. | 7 | → **Skip to D9b** |
| No such person in household/Not Applicable……. | -1 | → **Skip to D9b** |
| Don't Know…….. | -8 | → **Skip to D9b** |

i. Is (*name of participant*) MOTHER in the **primary household** self-employed?

| | |
|---|---|
| Yes…….. | 1 |
| No…….. | 2 |
| Don't Know…….. | -8 |

D9b. What is the current employment status of (*name of participant*) FATHER (including birth, adoptive or stepfather) in the **primary household**?

| | | |
|---|---|---|
| Working full-time (35 hours or more per week)…….. | 1 | |
| Working part-time (less than 35 hours per week)….. | 2 | |
| Unemployed but seeking work…….. | 3 | → **Skip to** D9c |
| Unemployed not seeking work…….. | 4 | → **Skip to** D9c |
| Student…….. | 5 | → **Skip to** D9c |
| Retired…….. | 6 | → **Skip to** D9c |
| Disability…….. | 7 | → **Skip to** D9c |
| No such person in household/Not Applicable……. | -1 | → **Skip to** D9c |
| Don't Know…….. | -8 | → **Skip to** D9c |

i. Is (*name of participant*)'s FATHER in the **primary household** self-employed?

| | |
|---|---|
| Yes…….. | 1 |
| No…….. | 2 |
| Don't Know…….. | -8 |

D9c. What is the current employment status of (*name of participant*)?

| | Yes | No | N/A | Don't Know |
|---|---|---|---|---|
| Working full-time (35 hours or more per week) …….. | 1 | 2 | -1 | -8 |
| Working part-time (less than 35 hours per week)…. | 1 | 2 | -1 | -8 |
| Disability income …….. | 1 | 2 | -1 | -8 |
| Student…….. | 1 | 2 | -1 | -8 |
| Unemployed but seeking work…….. | 1 **(skip to D10)** | 2 | -1 **(skip to D10)** | -8 **(skip to D10)** |
| Unemployed not seeking work…….. | 1 **(skip to D10)** | 2 | -1 **(skip to D10)** | -8 **(skip to D10)** |

i. Is (*name of participant*) self-employed?

Yes…… 1
No…… 2
Don't Know…… -8

D10. What is the zip code where the participant currently lives at least half of the time?

___ ___ ___ ___ ___ ___
Don't Know…… -8

D11. Has the participant lived at the current zip code for more than 1 year?

Yes…… 1 (skip to D12)
No…… 2
Don't Know…… -8 (Skip to Section E)

a. Approximately how many months has the participant lived at the current zip code?

___ ___ months

Don't Know…… -8

b. What was the zip code where the participant previously lived?

___ ___ ___ ___ ___ ___
Don't Know…… -8

c. Approximately, how many years did the participant live at the previous zip code?

___ ___ . ___ years **(Skip to Section E)**
Don't Know…… -8 **(Skip to Section E)**

D12. Approximately, how many years has the participant lived at the current zip code?

___ ___ . ___ years
Don't Know…… -8

D13. Is the participant's zip code and their parents/guardians' zip code the same?

Yes…… 1 **(Skip to Section E)**
No…… 2
Don't Know…… -8 **(Skip to Section E)**

D14. What is the current zip code of the parent(s)/guardian(s) (i.e., the parent(s)/guardian(s) home where the participant used to live at least half the time prior to living independently)?

___ ___ ___ ___ ___ ___
Don't Know…… -8

D15. Approximately, how long have the parent(s)/guardian(s) lived at the current zip code?

___ ___ year(s) ___ ___ month(s)

Don't Know…… -8

## SECTION E: PARTICIPANT'S FAMILY HISTORY

**The health conditions and illnesses experienced by close family members can provide important information about the participant's health. The following questions ask about the medical history of the participant's biological family. The participant's biological family includes his or her birth mother, birth father, grandparents, aunts, uncles, full brothers, full sisters and first cousins. (This does not include great aunts, great uncles and great grandparents.)** ***Full brothers and full sisters are defined as siblings who have the same birth mother and birth father as the participant.***

**Some people who lost their parents at an early age, or who were adopted, may not have information on their birth family. If you are familiar with the health history of any of the members of the participant's biological or birth family, please answer the following questions about these relatives' health to the extent that you are able. If you are uncertain of the answer to any question, please select "Don't Know." If you have trouble understanding anything, please feel free to ask for further clarification.**

E1. Do you have knowledge of the health history of any members of (*name of participant*) birth family (i.e. parents, grandparents, aunts, uncles, siblings and cousins)?

Yes…….. 1
No…….. 2 → **(Skip to F1)**

E2. a. How many **living half** siblings does (*name of participant*) have (Half siblings are defined as brothers and sisters, who have only one parent, either mother or birth father in common. Do not include deceased siblings.)?

___ ___ living half siblings → **(If "0", skip to E3)**
Don't Know …….. -8 → **(Skip to E3)**

b. Does (*name of participant*) have any **living half** siblings in the study?

Yes…….. 1
No…….. 2 → **(Skip to E3)**

i. How many **living half** siblings does (*name of participant*) have participating in the study?

___ ___ living half siblings

E3. a. How many **full** siblings does (*name of participant*) have? (Full siblings are defined as brothers and sisters, who have the same birth mother and birth father as the participant. Include deceased siblings.)

___ ___ full (living and deceased) siblings → **(If "0", skip to E5)**
Don't Know …….. -8 → **(Skip to E5)**

b. How many **living full** siblings does (*name of participant*) have?

___ ___ full (living) siblings → **(If "0", skip to E4)**
Don't Know …….. -8 → **(Skip to E4)**

c. Does (*name of participant*) have any **living full** siblings in the study?

Yes…….. 1
No…….. 2 → **(Skip to E4)**

i. How many **living full** siblings does (*name of participant*) have participating in the study?

___ ___ living full siblings

# FOLLOW-UP GENERAL HISTORY (F13)

E4. Please provide the date of birth for each of (*name of participant*) full siblings (brothers & sisters).

***START F07s1***

| | Date of Birth | | Date of Birth |
|---|---|---|---|
| a. Sibling 1 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) | e. Sibling 5 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) |
| | Don't Know..... -8 | | Don't Know..... -8 |
| b. Sibling 2 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) | f. Sibling 6 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) |
| | Don't Know..... -8 | | Don't Know..... -8 |
| c. Sibling 3 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) | g. Sibling 7 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) |
| | Don't Know..... -8 | | Don't Know..... -8 |
| d. Sibling 4 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) | h. Sibling 8 | ___ ___/ ___ ___/ ___ ___ ___ ___ (M M D D Y Y Y Y) |
| | Don't Know..... -8 | | Don't Know..... -8 |

***END F07s1***

**The next questions ask about the family members who were told they had kidney disease and the type of kidney disease they had.**

E5. a. In the past year, have any of **(*name of participant*) living or deceased biological family members** been told by a health care professional that they had kidney disease in the past year?

Yes..... 1
No..... 2 → **(Skip to E8)**
Don't know..... -8 → **(Skip to E8)**

**b.** Which family members? **c.** What type of kidney disease?

| | Yes | No | | Alport's Hereditary Nephritis | Polycystic Kidney Disease | Focal Segmental Glomerulosclerosis | Reflux Nephropathy (Kidney/bladder Reflux) | Other | Don't Know |
|---|---|---|---|---|---|---|---|---|---|
| 1 Mother..... | 1 | 2 | **(#2)** | 1 | 2 | 3 | 4 | 5 **(specify)** Specify: _____ | -8 |
| 2 Father..... | 1 | 2 | **(#3)** | 1 | 2 | 3 | 4 | 5 **(specify)** Specify: _____ | -8 |
| 3 Sibling (full brother or sister)..... | 1 | 2 | **(#4)** | 1 | 2 | 3 | 4 | 5 **(specify)** Specify: _____ | -8 |
| 4 Grandparent(s).... | 1 | 2 | **(#5)** | 1 | 2 | 3 | 4 | 5 **(specify)** Specify: _____ | -8 |
| 5 Aunt(s)/Uncle(s)... | 1 | 2 | **(#6)** | 1 | 2 | 3 | 4 | 5 **(specify)** Specify: _____ | -8 |
| 6 Cousin(s)..... | 1 | 2 | **(E6)** | 1 | 2 | 3 | 4 | 5 **(specify)** Specify: _____ | -8 |

**Next, the following questions ask about (*name of participant*) biological family members.**

E6. a. In the past year, have any of **(*name of participant*) living or deceased biological family members** been told by a health care professional that they had the SAME kidney disease as *(name of participant)*?

Yes..... 1

No..... 2 → **(Skip to E7)**

Don't know..... -8 → **(Skip to E7)**

b. Which biological family members? Yes No

**(Circle "Yes" or "No" for EACH of the following.)**

1. Mother..... 1 2
2. Father..... 1 2
3. Sibling (full brother or sister)..... 1 2
4. Grandparent(s)..... 1 2
5. Aunt(s)/Uncle(s)..... 1 2
6. Cousin(s)..... 1 2

E7. a. In the past year, have any of **(*name of participant*) living or deceased biological family members** had a kidney biopsy?

Yes..... 1

No..... 2 → **(Skip to E8)**

Don't know..... -8 → **(Skip to E8)**

b. Which biological family members? Yes No

**(Circle "Yes" or "No" for EACH of the following.)**

1. Mother..... 1 2
2. Father..... 1 2
3. Sibling (full brother or sister)..... 1 2
4. Grandparent(s)..... 1 2
5. Aunt(s)/Uncle(s)..... 1 2
6. Cousin(s)..... 1 2

E8. a. In the past year, have any of **(*name of participant*) living or deceased biological family members** been told by a health care professional (any doctor, nurse, physician assistant or nurse practitioner) that they had…

b. Which **biological family members**? **(Circle "Yes", "No", or "Don't Know" for EACH of the following)**

1. High Blood Pressure or Hypertension

Yes..... 1
No..... 2 → **(Skip to 2)**
Don't know..... -8 → **(Skip to 2)**

| | Yes | No | Don't Know |
|---|---|---|---|
| Mother..... | 1 | 2 | -8 |
| Father..... | 1 | 2 | -8 |
| Sibling (full brother or sister)..... | 1 | 2 | -8 |
| Grandparent(s)..... | 1 | 2 | -8 |
| Aunt(s)/Uncle(s)..... | 1 | 2 | -8 |
| Cousin(s)..... | 1 | 2 | -8 |

2. High Cholesterol

Yes..... 1
No..... 2 → **(Skip to 3)**
Don't know..... -8 → **(Skip to 3)**

| | Yes | No | Don't Know |
|---|---|---|---|
| Mother..... | 1 | 2 | -8 |
| Father..... | 1 | 2 | -8 |
| Sibling (full brother or sister)..... | 1 | 2 | -8 |
| Grandparent(s)..... | 1 | 2 | -8 |
| Aunt(s)/Uncle(s)..... | 1 | 2 | -8 |
| Cousin(s)..... | 1 | 2 | -8 |

3. Diabetes (high blood sugar or sugar diabetes)

Yes..... 1
No..... 2 → **(Skip to 4)**
Don't know..... -8 → **(Skip to 4)**

| | Yes | No | Don't Know |
|---|---|---|---|
| Mother..... | 1 | 2 | -8 |
| Father..... | 1 | 2 | -8 |
| Sibling (full brother or sister)..... | 1 | 2 | -8 |
| Grandparent(s)..... | 1 | 2 | -8 |
| Aunt(s)/Uncle(s)..... | 1 | 2 | -8 |
| Cousin(s)..... | 1 | 2 | -8 |

**(Circle "Yes", "No" or "Don't Know" for EACH of the following)**

4. Stroke before the age of 50

Yes..... 1
No..... 2 → **(Skip to 5)**
Don't know..... -8 → **(Skip to 5)**

| | Yes | No | Don't Know |
|---|---|---|---|
| Mother..... | 1 | 2 | -8 |
| Father..... | 1 | 2 | -8 |
| Sibling (full brother or sister)..... | 1 | 2 | -8 |
| Grandparent(s)..... | 1 | 2 | -8 |
| Aunt(s)/Uncle(s)..... | 1 | 2 | -8 |
| Cousin(s)..... | 1 | 2 | -8 |

5. Heart Attack before the age of 50

Yes..... 1
No..... 2 → **(Skip to E9)**
Don't know..... -8 → **(Skip to E9)**

| | Yes | No | Don't Know |
|---|---|---|---|
| Mother..... | 1 | 2 | -8 |
| Father..... | 1 | 2 | -8 |
| Sibling (full brother or sister)..... | 1 | 2 | -8 |
| Grandparent(s)..... | 1 | 2 | -8 |
| Aunt(s)/Uncle(s)..... | 1 | 2 | -8 |
| Cousin(s)..... | 1 | 2 | -8 |

**If more than one grandparent, aunt, uncle or cousin has had dialysis, ask your site coordinator for further instructions.**

E9. a. In the past year, have any of **(*name of participant*) living or deceased biological family members** had **dialysis** as treatment for kidney disease?

Yes..... 1
No..... 2 → **(Skip to E10)**
Don't Know.... -8 → **(Skip to E10)**

b. Which **biological family members**? (Circle "Yes", "No", or "Don't Know" for EACH of the following)

c. At what age was treatment started?

1. Mother — ___ ___ yrs old
Yes..... 1 — Don't Know..... -8
No..... 2 → **(skip to 2)**
Don't Know..... -8

2. Father — ___ ___ yrs old
Yes..... 1 — Don't Know..... -8
No..... 2 → **(skip to 3)**
Don't Know..... -8

3. Sibling (full brother or sister) — ___ ___ yrs old
Yes..... 1 — Don't Know..... -8
No..... 2 → **(skip to 4)**
Don't Know..... -8

4.Grandparents — ___ ___ yrs old
Yes..... 1 — Don't Know..... -8
No..... 2 → **(skip to 5)**
Don't Know..... -8

5. Aunts/Uncles — ___ ___ yrs old
Yes..... 1 — Don't Know..... -8
No..... 2 → **(skip to 6)**
Don't Know..... -8

6. Cousins — ___ ___ yrs old
Yes..... 1 — Don't Know..... -8
No..... 2 → **(skip to E10)**
Don't Know..... -8

**If more than one grandparent, aunt, uncle or cousin has had a kidney transplant, ask your site coordinator for further instructions.**

E10. a. In the past year, have any of **(*name of participant*) living or deceased biological family members** had a **kidney transplant** as treatment for kidney disease?

Yes..... 1
No..... 2 → **(Skip to E11)**
Don't Know.... -8 → **(Skip to E11)**

b. Which **biological family members**? (Circle "Yes", "No", or "Don't Know" for EACH of the following)

c. At what age was transplant performed?

1. Mother
Yes..... 1
No..... 2 → **(skip to 2)**
Don't Know..... -8
___ ___ yrs old
Don't Know..... -8

2. Father
Yes..... 1
No..... 2 → **(skip to 3)**
Don't Know..... -8
___ ___ yrs old
Don't Know..... -8

3. Sibling (full brother or sister)
Yes..... 1
No..... 2 → **(skip to 4)**
Don't Know..... -8
___ ___ yrs old
Don't Know..... -8

4.Grandparents
Yes..... 1
No..... 2 → **(skip to 5)**
Don't Know..... -8
___ ___ yrs old
Don't Know..... -8

5. Aunts/Uncles
Yes..... 1
No..... 2 → **(skip to 6)**
Don't Know..... -8
___ ___ yrs old
Don't Know..... -8

6. Cousins
Yes..... 1
No..... 2 → **(skip to E11)**
Don't Know..... -8
___ ___ yrs old
Don't Know..... -8

E11. In the past year, has the birth mother been pregnant?

Yes..... 1
No..... 2 **(skip to E13)**

E12. In the past year, have any of the birth mother's pregnancies resulted in the following?

**(Circle "Yes", "No" or "Don't Know" for EACH of the following)**

| | Yes | No | Don't Know |
|---|---|---|---|
| Stillbirth (fetus died at birth)..... | 1 | 2 | -8 |
| Miscarriage..... | 1 | 2 | -8 |

E13. In the past year, has (*name of participant*) birth mother had recurrent Urinary Tract Infections (UTI)?

Yes..... 1
No..... 2
Don't Know..... -8

E14. In the past year, has (*name of participant*) birth father had recurrent Urinary Tract Infections (UTI)?

Yes..... 1
No..... 2
Don't Know..... -8

E15. In the past year, have any of (*name of participant*) siblings had recurrent Urinary Tract Infections (UTI)?

Yes..... 1
No..... 2
Don't Know..... -8
N/A, participant does not have any siblings... -1

## SECTION F: PARTICIPANT'S DEVELOPMENTAL HISTORY

**The following questions are to learn more about the participant's development.**

F1. At the last CKiD study visit, was (*name of participant*) older than 5 years of age?

Yes..... 1 → **(Skip to F4)**
No…..... 2

F2. a. Is (*name of participant*) currently older than 5 years of age?

Yes..... 1 → **(Skip to F2c)**
No…..... 2

b. Is (*name of participant*) currently breast-fed?

Yes..... 1 → **(Skip to F3)**
No…..... 2
Don't Know……..…… -8 → **(Skip to F3)**

c. Was (*name of participant*) breast-fed?

Yes..... 1
No…..... 2 → **(Skip to F3)**
Don't Know……..…… -8 → **(Skip to F3)**

d. How old was (*name of participant*) when he/she was weaned from breast feeding?
**(Please circle "1" for years, "2" for months, "3" for weeks or "4" for days.)**

Age ___ ___ 1 = year(s)
2 = months
3 = week(s)
4 = days
Don't Know…… -8

F3. Is (*name of participant*) currently bottle-fed?

Yes..... 1 → **(Skip to F4)**
No…..... 2
Don't Know……..... -8 → **(Skip to F4)**

a. Was (*name of participant*) bottle-fed?

Yes..... 1
No…..... 2 → **(Skip to F4)**
Don't Know……..... -8 → **(Skip to F4)**

b. How old was (*name of participant*) when he/she was weaned from bottle feeding?
**(Please circle "1" for years, "2" for months, "3" for weeks or "4" for days)**

Age ___ ___ 1 = year(s)
2 = months
3 = week(s)
4 = days
Don't Know ……..... -8

**FOR QUESTION F4 – F5, PLEASE PAY CLOSE ATTENTION TO THE SKIP PATTERNS. FOLLOW EACH SKIP PATTERN CAREFULLY. IT IS IMPORTANT TO ANSWER EACH QUESTION ACCORDING TO THE SKIP PATTERN.**

F4. In the past year, has *(name of participant)* had any wetness or leakage of urine (accidents) during the day or night?

Yes..... 1
No..... 2 → **(Skip to c)**
Don't Know..... -8 → **(Skip to c)**

a. In the past year, is *(name of participant)* wet during the day?

Yes..... 1
No..... 2
Don't Know..... -8

b. In the past year, is *(name of participant)* wet during the night?

Yes..... 1
No..... 2
Don't Know..... -8

c. In the past year, has *(name of participant)* catheterized the bladder (i.e., put a tube in the bladder)?

Yes..... 1
No..... 2 → **(Skip to F5)**
Don't Know..... -8 → **(Skip to F5)**

i. In the past year, has *(name of participant)* catheterized through the urethra?

Yes..... 1
No..... 2
Don't Know..... -8

ii. In the past year, has *(name of participant)* catheterized through a stoma?

Yes..... 1
No..... 2
Don't Know..... -8

F5. At the last CKiD study visit, was (*name of participant*) toilet trained?

Yes..... 1 → **(Skip to F6)**
No..... 2
Don't Know..... -8 → **(Skip to F6)**

a. Is (*name of participant*) currently toilet trained?

Yes..... 1
No..... 2 → **(Skip to F6)**
Don't Know..... -8 → **(Skip to F6)**

b. When was (*name of participant*) toilet trained?

Age ___ ___ years

c. After toilet training, did bed-wetting occur?

Yes..... 1
No..... 2 → **(Skip to d)**
Don't Know..... -8 → **(Skip to d)**

i. Does bed-wetting still occur?

Yes..... 1 → **(Skip to iii)**
No..... 2
Don't Know..... -8 → **(Skip to c)**

ii. At what age did bed-wetting stop?
**(Please circle "1" for years and "2" for months)**

Age ___ ___ 1 = years
2 = months
Don't Know..... -8

iii. Were medical reasons the cause of bed-wetting?

Yes..... 1
No..... 2
Don't Know..... -8

d. After toilet training, did bed-soiling occur?
Yes..... 1
No..... 2 → **(Skip to F6)**
Don't Know..... -8 → **(Skip to F6)**

i. Does bed-soiling still occur?
Yes..... 1 → **(Skip to iii)**
No..... 2
Don't Know..... -8 → **(Skip to F6)**

ii. At what age did bed-soiling stop?
**(Please circle "1" for years and "2" for months)**
Age ___ ___ 1 = years
2 = months
Don't Know..... -8

iii. Were medical reasons the cause of bed-soiling?
Yes..... 1
No..... 2
Don't Know..... -8

F6. At the last CKiD study visit, was (*name of participant*) 4 years of age or older?
Yes..... 1 → **(Skip to F8)**
No..... 2
Don't Know..... -8

a. Is (*name of participant*) currently 4 years of age or older?
Yes..... 1
No..... 2 → **( Skip to F9)**
Don't Know..... -8 → **( Skip to F9)**

F7. During (*name of participant*) first 4 years, were any problems noted in the areas listed below? Indicate yes, no or don't know for each of the following.

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| a. | Eating | 1 | 2 | -8 |
| b. | Excessive crying | 1 | 2 | -8 |
| c. | Failure to thrive | 1 | 2 | -8 |
| d. | Motor skills | 1 | 2 | -8 |
| e. | Separating from parents | 1 | 2 | -8 |
| f. | Sleeping too little | 1 | 2 | -8 |
| g. | Sleeping too much | 1 | 2 | -8 |
| h. | Temper tantrums | 1 | 2 | -8 |

F8. Which hand does (*name of participant*) primarily use to write?

Primarily right..... 1
Primarily left..... 2
Ambidextrous (writes equally with both left and right hands)... 3

**If the participant is under 4 years old, please answer the next question based on whether a doctor or health care professional has told you that the participant has had any of the following problems.**

F9. Has (*name of participant*) experienced any of the following problems?
**(Circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| a. | Feeding problem | 1 | 2 | -8 |
| b. | Eating disorder | 1 | 2 | -8 |
| c. | Underweight problem | 1 | 2 | -8 |
| d. | Overweight problem | 1 | 2 | -8 |
| e. | Walking difficulty (per healthcare professional) | 1 | 2 | -8 |
| f. | Unclear speech (per healthcare professional) | 1 | 2 | -8 |
| g. | Sleep problem | 1 | 2 | -8 |
| h. | Colic | 1 | 2 | -8 |

**TO BE COMPLETED BY CLINICAL SITE:**

**DATE:** ___ ___/ ___ ___/ ___ ___ ___ ___ **INITIALS:** ___ ___ ___
M M / D D / Y Y Y Y

**ADMINISTRATION:** **1 = Interviewer Assisted**
**(Circle "1", "2" or "3")** **2 = Self-Administered**
**3 = Both**

# ABBREVIATED FOLLOW-UP GENERAL HISTORY (F13a)

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: ___ ___

A3. FORM VERSION: 0 3 / 0 1 / 1 8

A4. DATE OF VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. SITE COORDINATOR'S INITIALS: ___ ___ ___

A6. Is this study visit an irregular (accelerated) visit? Yes..... 1
No..... 2

A7. INDICATE PERSON COMPLETING THE FORM
Child/young adult..... 1
Parent or other adult..... 2
Both (Parent and Child/young adult) 3

***For each question, fill in the answer or circle the number that best matches the respondent's answer. Circle -8 for "Don't Know" responses. If a participant declines to answer a question, document -7 to the right of the response choice(s). For missing data, document -9 to the right of the response choice(s). Please document the reason for missing data (i.e., the question was accidentally skipped.)***

***Read each question and follow skip patterns as they appear on the form. Review the QxQ for detailed descriptions of questions.***

### INTRODUCTION TO PARTICIPANT:

**Thank you for participating in this study.**

**The following pages contain questions about your participant's family background and family medical history since their last study visit. Some of the questions may be difficult for you to answer and exact dates may be hard to remember. Please take as much time as you need, so I can gather information that is as accurate as possible.**

**As with all study information, your responses will be kept strictly confidential, and the responses you provide will in no way affect the participant's clinical care. The first set of questions asks about you and the participant's background. If you have trouble understanding anything, please feel free to ask for further clarification.**

## SECTION B: INFORMATION ABOUT YOU

**The following questions are about your relationship to the participant who is participating in the study.**

B1. What is your relationship to (*name of participant*)?

| | | |
|---|---|---|
| Mother..... | 1 | → **(Skip to C1)** |
| Father..... | 2 | → **(Skip to C1)** |
| Legal Guardian..... | 3 | → **(Skip to C1)** |
| Self……..…….. | 5 | → **(Skip to C1)** |
| Other..... | 4 | |

a. If **OTHER,** specify your relationship: _____

(Such as: grandmother, stepfather, uncle, etc.)

## SECTION C: PARTICIPANT'S EDUCATION

**The following questions are about the participant's education. Specifically, the next question asks about the highest grade or level of school the participant has completed. For example, if the participant is currently in the 12th grade, then enter "11", or if the participant is currently in the 6th grade, then enter "5". In addition, if the participant is in the 1st grade, kindergarten or pre-school/pre-K, then enter "0" or if participant is a sophomore in college, then enter "13".**

C1. What is the **highest** grade or level of school that (*name of participant*) has COMPLETED?

___ ___Grade

Don't Know…….…….. -8

Not Applicable/child less than 5 years old
and does not attend pre-school/pre-k……. -1

C2. Does (*name of participant*) attend school (including pre-school and pre-K) outside of the home?

| | | |
|---|---|---|
| Yes……..…..... | 1 | |
| No……..... | 2 | → **(Skip to D1)** |

C3. During the past school year, approximately how many days has (*name of participant*) missed from school because of not feeling well?

___ ___ Days

Don't Know……..…….. -8

**The next two questions refer to service(s) the participant is currently receiving unless this form is completed during the summertime when school is not in session. If this form is completed during the summer months, please refer to the service(s) the participant received during the past school year.**

C4. Does (name of participant) have an individualized educational plan (IEP)? (An individualized educational plan includes special education and related services designed to address specific educational needs of children with disabilities. REFER TO QXQ FOR DETAILED DESCRIPTION.)

Yes…… 1
No…… 2
Don't Know…… -8
Not Applicable/child less than 5 years old…… -1 → **(Skip to D1)**

C5. Does (name of participant) have a 504 plan at school (or equivalent for Canadian sites)? (A 504 plan is a program designed to assist students with physical or emotional disabilities or other special needs in a regular school environment. REFER TO QXQ FOR DETAILED DESCRIPTION.)

Yes…… 1
No…… 2
Don't Know…… -8

## SECTION D: PARTICIPANT'S FAMILY AND PRIMARY HOUSEHOLD

**The following questions are to learn more about the participant's home and with whom he or she lives.**

D1. What is the current relationship between (*name of participant*) **biological parents**?

Not married, living together…… 1
Married, living together…… 2
Married, separated…… 3
Widowed…… 4
Divorced…… 5
Never married, not living together…… 6
Refuse to answer…… -7
Don't Know…… -8

# ABBREVIATED FOLLOW-UP GENERAL HISTORY (F13a)

**The following questions ask about the participant's primary household. The primary household is the parent/guardian's home in which the participant lives at least half of the time. If the participant does not live with a parent/guardian (living independently, attending college or boarding school, emancipated, etc.), then the primary household is the parent/guardian's home where the participant used to live at least half the time prior to living independently.**

D2. How many days per week does (*name of participant*) live in the primary household?
Indicate a number between 4 and 7. (For participants who do not live with a parent/guardian, indicate the number of days the participant lived in parent/guardian's home prior to living independently.)

____ days

Don't Know..... -8

D3. How many people live in the primary household at least half the time?

___ ___ people

Don't Know..... -8

D4. How many adults live in the primary household at least half the time? An adult is a person at least 18 years of age. Include **all persons at least 18 years of age**, including siblings and non-relatives. Include participant if 18 years of age.

___ ___ adults

Don't Know..... -8

D5. Which of the following adults (18 years of age or older) live in the primary household at least half the time? Include the participant, if applicable. **(Circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| a. | Birth Mother..... | 1 | 2 | -8 |
| b. | Birth Father..... | 1 | 2 | -8 |
| c. | Step Mother/ Adoptive Mother..... | 1 | 2 | -8 |
| d. | Step Father/ Adoptive Father..... | 1 | 2 | -8 |
| e. | Participant..... | 1 | 2 | -8 |
| f. | Other..... | 1 | 2 **(Skip to D6)** | -8 **(Skip to D6)** |
| | i. Specify: _____ | | | |

D6. Do any of the people, adults or children, living in the primary household at least half the time routinely smoke cigarettes, cigars, cigarillos or little cigars?

Yes..... 1
No..... 2
Don't Know..... -8

**Deleted Questions D7 and D8.**

**For D9: ALLOW RESPONDENT TO CIRCLE THE NUMBER IN THE FAR RIGHT COLUMN THAT CORRESPONDS TO THEIR TOTAL INCOME.**

D9. Please estimate the total income (before taxes) of all members of the **primary household**. Include **total income from wages, business, or investments** for all members of (*name of participant*) primary household, by year, month, or week. Do **NOT** include social security, disability insurance, or other governmental assistance. **Circle** the number in the FAR RIGHT COLUMN that corresponds to the total income.

| YEAR | MONTH | WEEK | |
|---|---|---|---|
| $6,000 OR LESS | $500 OR LESS | $115 OR LESS | **1** |
| $6,001 TO $12,000 | $501 TO $1,000 | $116 TO $231 | **2** |
| $12,001 TO $18,000 | $1,001 TO $1,500 | $232 TO $346 | **3** |
| $18,001 TO $24,000 | $1,501 TO $2,000 | $347 TO $461 | **4** |
| $24,001 TO $30,000 | $2,001 TO $2,500 | $462 TO $577 | **5** |
| $30,001 TO $36,000 | $2,501 TO $3,000 | $578 TO $692 | **6** |
| $36,001 TO $75,000 | $3,001 TO $6,250 | $693 TO $1442 | **7** |
| MORE THAN $75,000 | MORE THAN $6,250 | MORE THAN $1442 | **8** |
| Don't know | | | **-8** |

D9a. What is the current employment status of (*name of participant*) MOTHER (including birth, adoptive or stepmother) in the **primary household**?

| | | |
|---|---|---|
| Working full-time (35 hours or more per week) | 1 | |
| Working part-time (less than 35 hours per week) | 2 | |
| Unemployed but seeking work | 3 | → **Skip to D9b** |
| Unemployed not seeking work | 4 | → **Skip to D9b** |
| Student | 5 | → **Skip to D9b** |
| Retired | 6 | → **Skip to D9b** |
| Disability | 7 | → **Skip to D9b** |
| No such person in household/Not Applicable | -1 | → **Skip to D9b** |
| Don't Know | -8 | → **Skip to D9b** |

i. Is (*name of participant*) MOTHER in the **primary household** self-employed?

| | |
|---|---|
| Yes | 1 |
| No | 2 |
| Don't Know | -8 |

D9b. What is the current employment status of (*name of participant*) FATHER (including birth, adoptive or stepfather) in the **primary household**?

| | | |
|---|---|---|
| Working full-time (35 hours or more per week) | 1 | |
| Working part-time (less than 35 hours per week) | 2 | |
| Unemployed but seeking work | 3 | → **Skip to D9c** |
| Unemployed not seeking work | 4 | → **Skip to D9c** |
| Student | 5 | → **Skip to D9c** |
| Retired | 6 | → **Skip to D9c** |
| Disability | 7 | → **Skip to D9c** |
| No such person in household/Not Applicable | -1 | → **Skip to D9c** |
| Don't Know | -8 | → **Skip to D9c** |

i. Is (*name of participant*)'s FATHER in the **primary household** self-employed?

Yes..... 1
No..... 2
Don't Know..... -8

D9c. What is the current employment status of (*name of participant*)?

| | Yes | No | N/A | Don't Know |
|---|---|---|---|---|
| Working full-time (35 hours or more per week) ..... | 1 | 2 | -1 | -8 |
| Working part-time (less than 35 hours per week).... | 1 | 2 | -1 | -8 |
| Disability income..... | 1 | 2 | -1 | -8 |
| Student..... | 1 | 2 | -1 | -8 |
| Unemployed but seeking work..... | 1 **(skip to D10)** | 2 | -1 **(skip to D10)** | -8 **(skip to D10)** |
| Unemployed not seeking work..... | 1 **(skip to D10)** | 2 | -1 **(skip to D10)** | -8 **(skip to D10)** |

i. Is (*name of participant*) self-employed?

Yes..... 1
No..... 2
Don't Know..... -8

D10. What is the zip code where the participant currently lives at least half of the time)?

___ ___ ___ ___ ___ ___
Don't Know..... -8

D11. Has the participant lived at the current zip code for more than 1 year?

Yes..... 1 **(Skip to D12)**
No..... 2
Don't Know..... -8 **(Skip to F1)**

a. Approximately how many months has the participant lived at the current zip code?

___ ___ months
Don't Know..... -8

b. What was the zip code where the participant previously lived?

___ ___ ___ ___ ___ ___
Don't Know..... -8

c. Approximately, how many years did the participant live at the previous zip code?

___ ___ . ___ years **(Skip to F1)**
Don't Know..... -8 **(Skip to F1)**

D12. Approximately, how many years has the participant lived at the current zip code?

___ ___ . ___ years
Don't Know..... -8

D13. Is the participant's zip code and their parents/guardians' zip code the same?

Yes..... 1 **(Skip to F1)**
No..... 2
Don't Know..... -8 **(Skip to F1)**

D14. What is the current zip code of the parent(s)/guardian(s) (i.e., the parent(s)/guardian(s) home where the participant used to live at least half the time prior to living independently)?

___ ___ ___ ___ ___ ___
Don't Know..... -8

D15. Approximately, how long have the parent(s)/guardian(s) lived at the current zip code?

___ ___ year(s) ___ ___ month(s)

Don't Know..... -8

**Deleted Section E.**

## SECTION F: PARTICIPANT'S DEVELOPMENTAL HISTORY

**The following questions are to learn more about the participant's development.**

F1. At the last CKiD study visit, was (*name of participant*) older than 5 years of age?

Yes..... 1 → **(Skip to F4)**
No..... 2

F2. a. Is (*name of participant*) currently older than 5 years of age?

Yes..... 1 → **(Skip to F2c)**
No..... 2

b. Is (*name of participant*) currently breast-fed?

Yes..... 1 → **(Skip to F3)**
No..... 2
Don't Know..... -8 → **(Skip to F3)**

c. Was (*name of participant*) breast-fed?

Yes..... 1
No..... 2 → **(Skip to F3)**
Don't Know..... -8 → **(Skip to F3)**

d. How old was (*name of participant*) when he/she was weaned from breast feeding?
**(Please circle "1" for years, "2" for months, "3" for weeks or "4" for days.)**

Age ___ ___ 1 = year(s)
2 = months
3 = week(s)
4 = days

Don't Know..... -8

F3. Is (*name of participant*) currently bottle-fed?

Yes..... 1 → **(Skip to F4)**
No..... 2
Don't Know..... -8 → **(Skip to F4)**

a. Was (*name of participant*) bottle-fed?
Yes..... 1
No..... 2 → **(Skip to F4)**
Don't Know..... -8 → **(Skip to F4)**

b. How old was (*name of participant*) when he/she was weaned from bottle feeding?
**(Please circle "1" for years, "2" for months, "3" for weeks or "4" for days)**

Age ___ ___ 1 = year(s)
2 = months
3 = week(s)
4 = days

Don't Know ..... -8

**FOR QUESTION F4 – F5, PLEASE PAY CLOSE ATTENTION TO THE SKIP PATTERNS. FOLLOW EACH SKIP PATTERN CAREFULLY. IT IS IMPORTANT TO ANSWER EACH QUESTION ACCORDING TO THE SKIP PATTERN.**

F4. In the past year, has *(name of participant)* had any wetness or leakage of urine (accidents) during the day or night?

Yes..... 1
No..... 2 → **(Skip to c)**
Don't Know..... -8 → **(Skip to c)**

a. In the past year, is *(name of participant)* wet during the day?

Yes..... 1
No..... 2
Don't Know..... -8

b. In the past year, is *(name of participant)* wet during the night?

Yes..... 1
No..... 2
Don't Know..... -8

c. In the past year, has *(name of participant)* catheterized the bladder (i.e., put a tube in the bladder)?
Yes..... 1
No..... 2 → **(Skip to F5)**
Don't Know..... -8 → **(Skip to F5)**

i. In the past year, has *(name of participant)* catheterized through the urethra?

Yes..... 1
No..... 2
Don't Know..... -8

ii. In the past year, has *(name of participant)* catheterized through a stoma?

Yes……..…..... 1

No……..…….. 2

Don't Know……..…. -8

F5. At the last CKiD study visit, was (*name of participant*) toilet trained?

Yes……..…..... 1 → **(Skip to F6)**

No……..…….. 2

Don't Know……..…..... -8 → **(Skip to F6)**

a. Is (*name of participant*) currently toilet trained?

Yes……..…..... 1

No……..…….. 2 → **(Skip to F6)**

Don't Know……..…..... -8 → **(Skip to F6)**

b. When was (*name of participant*) toilet trained?

Age ___ ___ years

c. After toilet training, did bed-wetting occur?

Yes……..…..... 1

No……..…….. 2 → **(Skip to d)**

Don't Know……..…..... -8 → **(Skip to d)**

i. Does bed-wetting still occur?

Yes……..…..... 1 → **(Skip to iii)**

No……..…….. 2

Don't Know……..…. -8 → **(Skip to c)**

ii. At what age did bed-wetting stop?
**(Please circle "1" for years and "2" for months)**

Age ___ ___ 1 = years
2 = months

Don't Know…….. -8

iii. Were medical reasons the cause of bed-wetting?

Yes……..…..... 1

No……..…….. 2

Don't Know……..…. -8

d. After toilet training, did bed-soiling occur?
Yes..... 1
No..... 2 → **(END)**
Don't Know..... -8 → **(END)**

i. Does bed-soiling still occur?
Yes..... 1 → **(Skip to iii)**
No..... 2
Don't Know..... -8 → **(END)**

ii. At what age did bed-soiling stop?
**(Please circle "1" for years and "2" for months)**
Age ___ ___ 1 = years
2 = months
Don't Know..... -8

iii. Were medical reasons the cause of bed-soiling?
Yes..... 1
No..... 2
Don't Know..... -8

**Deleted Questions F6, F7, F8, F9 and Section G.**

---

**TO BE COMPLETED BY CLINICAL SITE:**

**DATE:** ___ ___/ ___ ___/ ___ ___ ___ ___ **INITIALS:** ___ ___ ___
M M / D D / Y Y Y Y

**ADMINISTRATION:** **1 = Interviewer Assisted**
**(Circle "1", "2" or "3")** **2 = Self-Administered**
**3 = Both**

# MEDICAL HISTORY (MH)

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: 0 1 a

A3. FORM VERSION: 0 3 / 0 1 / 1 8

A4. DATE OF VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. SITE COORDINATOR'S INITIALS: ___ ___ ___

A6. INDICATE PERSON COMPLETING THE FORM

| | |
|---|---|
| Child/young adult..... | 1 |
| Parent or other adult..... | 2 |
| Both (Parent and Child/young adult) | 3 |

***For each question, fill in the answer or circle the number that best matches the respondent's answer. Circle -8 for "Don't Know" responses. If a participant declines to answer a question, document -7 to the right of the response choice(s). For missing data, document -9 to the right of the response choice(s). Please document the reason for missing data (i.e., the question was accidentally skipped.)***

***Read each question and follow skip patterns as they appear on the form. Review the QxQ for detailed descriptions of questions.***



### INTRODUCTION TO PARTICIPANT:

**The following questions are about the participant's health history, including information about the current and past diseases that the participant may have had in life. Dates may be hard to remember. Please take as much time as you need so I can gather information that is as accurate as possible.**

**As with all study information, your responses will be kept strictly confidential, and the responses you provide will in no way affect the participant's clinical care. The first set of questions asks about the participant's kidney disease. Whenever the term "health care provider" is used, it means any doctor, nurse, physician assistant or nurse practitioner the child has ever seen. If you have trouble understanding anything, please feel free to ask for further clarification.**

## SECTION B: KIDNEY DISEASE

B1. When did the mother or another family member first become aware of (*name of participant*) kidney problem?

During Pregnancy..... 1 **(Skip to B4)**

After Pregnancy..... 2

Don't Know..... -8

**DELETED D2**

B3. How old was (*name of participant*) when you or another family member first became aware of his/her kidney problem?
**(Please circle "1" for years, "2" for months, "3" for weeks or "4" for days.)**

age ___ ___

1 = years
2 = months
3 = weeks
4 = days

Don't Know..... -8

B4. How old was (*name of participant*) when he or she was first seen by a pediatric nephrologist?
**(Please circle "1" for years, "2" for months, "3" for weeks or "4" for days.)**

age ___ ___

1 = years
2 = months
3 = weeks
4 = days

Don't Know..... -8

B5. Has *(name of participant)* been seen by a Urologist (adult or pediatric)?

Yes..... 1

No..... 2 **(Skip to B6)**

a. How old was (*name of participant*) when he or she was first seen by a Urologist (adult or pediatric)? **(Please circle "1" for years, "2" for months, "3" for weeks or "4" for days.)**

age ___ ___

1 = years
2 = months
3 = weeks
4 = days

Don't Know..... -8

B6. What were the methods/procedures performed to determine the **primary** diagnosis of *(name of participant)* with chronic kidney disease?

**(Please circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| a. | Kidney Biopsy…… | 1 | 2 | -8 |
| b. | Ultrasound/sonogram…… | 1 | 2 | -8 |
| c. | Voiding Cystourethrogram (VCUG) …… | 1 | 2 | -8 |
| d. | Nuclear Medicine Study (i.e., DMSA, DTPA, MAG3)…… | 1 | 2 | -8 |
| e. | Intravenous Pyelogram (IVP)…… | 1 | 2 | -8 |
| f. | Magnetic Resonance Imaging (MRI)…… | 1 | 2 | -8 |
| g. | Computed Tomography Scan (Cat/CT Scan)…… | 1 | 2 | -8 |
| h. | Genetic Testing…… | 1 | 2 | -8 |
| i. | Other…… | 1 | 2 | -8 |
| | | | **(Skip to B7)** | **(Skip to B7)** |

1. Specify Other method/procedure: _____

**PROMPT: IF ANY OF B7 – B8 = YES, THEN COMPLETE THE MEDICAL ABSTRACTION TRACKING FORM (MAT).**

B7. Has (*name of participant*) ever had a urologic procedure, including surgery to treat his or her kidney problems?

Yes…… 1 → **(Complete MAT )**

No…… 2

Don't Know…… -8

B8. Has (*name of participant*) ever had a genetic test (i.e., Podocin or Nephrin) performed to help diagnose his or her kidney disease?

Yes…… 1 → **(Complete MAT )**

No…… 2

Don't Know…… -8

B9. Has a healthcare provider ever diagnosed (*name of participant*) with a kidney infection with a fever?

Yes..... 1

No..... 2 **(Skip to B10)**

Don't Know..... -8 **(Skip to B10)**

a. How many times did he/she have a kidney infection with a fever in his/her first year of life?

___ ___ times

Don't Know..... -8

b. How many times did he/she have a kidney infection with a fever during the last year?

___ ___ times

Don't Know..... -8

B10. Is participant a female?

Yes..... 1

No..... 2 **(Skip to C1)**

B11. Has (*name of participant*) started her menses (i.e. period)?

Yes..... 1

No..... 2 **(Skip to C1)**

Don't Know..... -8 **(Skip to C1)**

a. How old was she when she started her menses (i.e. period)?

___ ___ years

Don't Know..... -8

## SECTION C: GENERAL MEDICAL HISTORY

**The next set of questions asks about diseases/illnesses that the participant had since birth and diseases/illness that the participant has developed.**

Has a doctor or any other healthcare professional ever told you that (*name of participant*) has any of the following diseases/illnesses?

**PROMPT: IF ANY OF C1 – C4 = "YES", THEN COMPLETE THE MEDICAL ABSTRACTION TRACKING FORM (MAT).**

**(Please circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| C1. | GENERAL / METABOLIC DISEASE | | | |
| | a. Diabetes Mellitus (Sugar Diabetes, High Blood Sugar) | 1 | 2 | -8 |
| | b. Sickle Cell Disease | 1 | 2 | -8 |
| | c. Auto-immune Disease (Lupus, Rheumotid Arthritis) | 1 | 2 | -8 |
| C2. | CARDIOVASCULAR DISEASE | | | |
| | a. Heart Failure (Congestive heart failure) | 1 | 2 | -8 |
| | b. Stroke | 1 | 2 | -8 |
| | c. Left Ventricular Hypertrophy (LVH)/ Thickened Heart Muscle | 1 | 2 | -8 |
| C3. | LUNG DISEASE | | | |
| | a. Asthma | 1 | 2 | -8 |
| | b. Chronic Lung Disease | 1 | 2 | -8 |
| | c. Bronchopulmonary Dysplasia (BPD) | 1 | 2 | -8 |
| C4. | GENITOURINARY DISEASE | | | |
| | a. Urinary Tract Infection | 1 | 2 | -8 |
| | b. Blood in urine | 1 | 2 | -8 |
| | c. Protein in urine | 1 | 2 | -8 |
| | d. Passage of kidney stones | 1 | 2 | -8 |
| | e. Recurrent pain on urinating | 1 | 2 | -8 |
| C5. | GASTROINTESTINAL DISEASE | | | |
| | a. Gastroenteritis (stomach flu, food poisoning) | 1 | 2 | -8 |
| | b. Gastroesophageal Reflux (GERD) | 1 | 2 | -8 |
| | c. Gastrointestinal Ulcer | 1 | 2 | -8 |
| | d. Gastrointestinal Bleeding | 1 | 2 | -8 |
| | e. Liver Inflammation Non-Infectious | 1 | 2 | -8 |
| | f. Fatty Liver | 1 | 2 | -8 |
| | g. Irritable Bowel | 1 | 2 | -8 |
| | h. Encopresis (constipation) | 1 | 2 | -8 |

C6. Has a doctor or healthcare professional ever told you that (*name of participant*) has hypertension (high blood pressure)?

Yes..... 1 → Complete MAT
No..... 2 **(Skip to C7)**
Don't Know..... -8 **(Skip to C7)**

a. What is the status hypertension?

On meds but BP still high (Continued problem) 1
No longer hypertensive (Resolved problem) 2
On meds and BP controlled (Controlled w/ meds) 3

b. Was the hypertension diagnosed within the past year?

Yes..... 1
No..... 2
Don't Know..... -8

C7. Has a doctor or healthcare professional told you that (*name of participant*) has hepatitis?

Yes..... 1 → Complete MAT
No..... 2 **(Skip to C8)**
Don't Know..... -8 **(Skip to C8)**

a. Which of the following types of hepatitis does (name of participant) have?

| | Yes | No | Don't Know |
|---|---|---|---|
| Type A | 1 | 2 | -8 |
| Type B | 1 | 2 | -8 |
| Type C | 1 | 2 | -8 |
| Other type | 1 | 2 **(Skip to C7b)** | -8 **(Skip to C7b)** |

Specify: _____

b. Was the hepatitis diagnosed within the past year?

Yes..... 1
No..... 2
Don't Know..... -8

C8. Has a doctor or healthcare professional told you that (*name of participant*) has any other infection(s)?

Yes..... 1 → Complete MAT
No..... 2 **(Skip to C9)**
Don't Know..... -8 **(Skip to C9)**
Specify: _____

a. Was the infection diagnosed within the past year?

No..... 1
Don't Know..... 2
Don't Know ..... -8

**(Please circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| C9. | CANCER | | | |
| a. | Leukemia | 1 | 2 | -8 |
| b. | Lymphoma | 1 | 2 | -8 |
| c. | Bone Cancer | 1 | 2 | -8 |
| d. | Liver Cancer | 1 | 2 | -8 |
| e. | Skin Cancer | 1 | 2 | -8 |
| f. | Soft Tissue Sarcomas | 1 | 2 | -8 |
| g. | Other | 1 | 2 **(Skip to C10)** | -8 **(Skip to C10)** |
| | Specify:_____ | | | |

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| C10. | NEUROPSYCHIATRIC DISEASE | | | |
| a. | Attention Deficit Disorder (ADD) | 1 | 2 | -8 |
| b. | Attention Deficit Hyperactivity Disorder (ADHD) | 1 | 2 | -8 |
| c. | Depression | 1 | 2 | -8 |
| d. | Learning Disability other than ADD or ADHD | 1 | 2 | -8 |
| e. | Anxiety Disorder | 1 | 2 | -8 |
| f. | Other | 1 | 2 **(Skip to C11)** | -8 **(Skip to C11)** |
| | Specify:_____ | | | |

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| C11. | CHILDHOOD ILLNESSES | | | |
| a. | Measles | 1 | 2 | -8 |
| b. | German Measles | 1 | 2 | -8 |
| c. | Mumps | 1 | 2 | -8 |
| d. | Chickenpox | 1 | 2 | -8 |
| e. | Tuberculosis | 1 | 2 | -8 |
| f. | Whooping Cough | 1 | 2 | -8 |
| g. | Scarlet Fever | 1 | 2 | -8 |
| h. | Rheumatic Fever | 1 | 2 | -8 |
| i. | Diphtheria | 1 | 2 | -8 |
| j. | Meningitis | 1 | 2 | -8 |
| k. | Encephalitis | 1 | 2 | -8 |
| l. | Anemia | 1 | 2 | -8 |
| m | Fever above 104° for greater than 2 days | 1 | 2 | -8 |
| n. | Head injury including brain bleed | 1 | 2 | -8 |
| o. | Coma or loss of consciousness | 1 | 2 | -8 |
| p. | Other | 1 | 2 **(Skip to C10)** | -8 **(Skip to C10)** |

Specify:_____

Please indicate whether (*name of participant*) has or has had any of the following problems.
**(Please circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | Yes | No | Don't Know |
|---|---|---|---|
| C12. NEUROLOGICAL | | | |
| a. Seizures/Convulsions | 1 | 2 | -8 |
| b. Speech Defects | 1 | 2 | -8 |
| c. Accident Prone | 1 | 2 | -8 |
| d. Bites Nails | 1 | 2 | -8 |
| e. Sucks Thumb | 1 | 2 | -8 |
| f. Grinds Teeth | 1 | 2 | -8 |
| g. Twitches/Tics | 1 | 2 | -8 |
| h. Bangs Head | 1 | 2 | -8 |
| i. Rocks Back and Forth | 1 | 2 | -8 |
| j. Bowel Movements in Bed/Pants | 1 | 2 | -8 |
| C13. HEARING | | | |
| a. Ear Infections | 1 | 2 | -8 |
| b. Hearing Problems | 1 | 2 | -8 |
| c. Ear Tubes | 1 | 2 | -8 |
| C14. VISION | | | |
| a. Vision Problems | 1 | 2 | -8 |
| b. Wears Glasses/Contacts | 1 | 2 | -8 |
| c. Color Blindness | 1 | 2 | -8 |

## SECTION D: ORTHOPEDIC HISTORY

**The next set of questions asks about any orthopedic injuries the participant may currently have or that the participant has had since birth. Orthopedic injuries are injuries to the bones.**

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| D1. | Has a doctor or any other health professional ever told you that (name of participant) has had any broken bones? | 1 | 2 **(Skip to D2)** | -8 **(Skip to D2)** |

a. Please indicate which of the following bones (name of participant) has broken.
**(Please circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| 1. | Back..... | 1 | 2 | -8 |
| 2. | Shoulder..... | 1 | 2 | -8 |
| 3. | Arm/Elbow..... | 1 | 2 | -8 |
| 4. | Wrist/Hand..... | 1 | 2 | -8 |
| 5. | Hip..... | 1 | 2 | -8 |
| 6. | Knee..... | 1 | 2 | -8 |
| 7. | Ankle..... | 1 | 2 | -8 |
| 8. | Foot..... | 1 | 2 | -8 |
| 9. | Leg..... | 1 | 2 | -8 |
| 10. | Fingers..... | 1 | 2 | -8 |
| 11. | Toes..... | 1 | 2 | -8 |
| 12. | Ribs..... | 1 | 2 | -8 |
| 13. | Collar Bone..... | 1 | 2 | -8 |

D2. Does (*name of participant*) have any bone disease in the hips?

Yes..... 1 → **(Complete MAT )**

No..... 2 **(Skip to F1)**

Don't Know..... -8 **(Skip to F1)**

a. Was the bone disease diagnosed within the past year?

Yes..... 1 → **(Complete MAT )**

No..... 2

Don't Know..... -8

## DELETED SECTION E

## SECTION F: HEALTHCARE UTILIZATION

**These questions ask about all the places the participant may have received care in the last year.**

F1. In the past year, where has (*name of participant*) gone to receive medical care? **(Please circle "Yes" or "No" for EACH of the following places.)**

Did (name of participant) go to…

| | | Yes | No |
|---|---|---|---|
| a. | A clinic or health care center | 1 | 2 |
| b. | A private doctor's office | 1 | 2 |
| c. | Hospital Outpatient Department | 1 | 2 |
| d. | The emergency room | 1 | 2 **(Skip to e)** |
| | 1. How many times has (name of participant) received care at the emergency room in the last year? ___ ___ | | |
| e. | Some other place | 1 | 2 **(Skip to F2)** |
| | 1. Please specify: _____ | | |

**These questions ask about the participant's use of health care. In this set of questions, the term "health care provider" means any doctor, nurse practitioner, or physician's assistant you may go to for medical care.**

F2. In the past year, how many times did (*name of participant*) see a health care provider, not including this CKID study visit or the visit at which you were screened for eligibility into the study? Include well child visits, sick visits and ER visits. **Do not include** times when (name of participant) was hospitalized overnight.

___ ___ times

Don't Know..... -8

F3. In the past year, when you or (*name of participant*) went for medical care, did he/she usually (more than half of the time) see the same health care provider or group of providers for his/her medical appointments?

Yes..... 1

No..... 2

Don't Know..... -8

# MEDICAL HISTORY (MH)

**The next questions ask about hospitalizations. Being hospitalized includes staying overnight or being admitted for a procedure that was done in one day. Please include all medical and psychiatric hospitalizations. This does not include being treated in the emergency room and then released the same day.**

F4. In the past year, has (*name of participant*) been hospitalized (apart from when he or she was born)? Do not include overnight stays in the emergency room.

Yes ..... 1 → **(Complete MAT )**
No ..... 2 **(Skip to F5)**
Don't Know ..... -8 **(Skip to F5)**

a. How many different times was (*name of participant*) hospitalized during the past year?
___ ___ times
Don't Know ..... -8

**These questions ask some questions about care or social services that the participant may have received in the last year.**

F5. In the past year, has (*name of participant*) been seen by a social worker or a case manager to help him/her obtain services?

Yes ..... 1
No ..... 2

F6. In the past year, has (*name of participant*) received care or services from a psychologist, psychiatrist, psychiatric nurse, counselor, or other mental health professional?

Yes ..... 1
No ..... 2

F7. In the past year, has an agency assisted (*name of participant*) with food, such as food stamps or WIC, meals on wheels, food pantries, or arranged to have groceries delivered to the participant's parent/guardian's primary household (i.e., the home in which the participant lives at least half the time or lived prior to living independently)?

Yes ..... 1
No ..... 2

F8. In the past year, has a social service agency helped you or (*name of participant*) find a place to live?

Yes ..... 1
No ..... 2

F9. In the past year, has (*name of participant*) received care from a dentist or dental hygienist?

Yes ..... 1
No ..... 2

F10. In the past year, has (*name of participant*) seen a nutritionist or a dietician?

Yes ..... 1
No ..... 2

## SECTION G: HEALTH INSURANCE

**These questions ask about the participant's health care coverage.**

G1. Does (*name of participant*) currently have any kind of health insurance or health care coverage? This includes both private and public insurance programs (e.g., Medicaid, SCHIP or MCHIP), dental insurance, and programs that help pay for medications.

Yes ..... 1 **(Skip to G1b)**
No ..... 2

G1a. How long has it been since (name of participant) last had ANY health insurance or coverage?

6 months or less ..... 1 **(skip to G14)**
More than 6 months, but no more than 1 yr ago..... 2 **(skip to G14)**
More than 1 year, but no more than 3 years ago..... 3 **(skip to G14)**
More than 3 years..... 4 **(skip to G14)**
Never had health insurance or coverage..... 5 **(skip to G14)**
Don't know..... -8 **(skip to G14)**

G1b. In the past year, was there any time when (name of participant) was not covered by ANY health insurance or coverage?

Yes ..... 1
No ..... 2 **(skip to G2)**

G1c. In the past year, about how long was (name of participant) without ANY health insurance or coverage?

__ __ 1 = months 2 = weeks 3 = days

G1d. In the past year, was (name of participant) not covered by ANY insurance or coverage?

Yes ..... 1
No ..... 2

# MEDICAL HISTORY (MH)

**INSTRUCTIONS: ASK QUESTIONS G2 - G15. IF THE RESPONSE IS YES (CODE 1) ASK QUESTION "A" (FAR RIGHT COLUMN) UNLESS THE BOX IS SHADED.**

| Does (*name of participant*) currently have... | YES | NO | NA | **A.** Do you or your family members pay for any of the insurance premium? YES | NO |
|---|---|---|---|---|---|
| G2. *CALIFORNIA ONLY: Medi-CAL? | 1 | 2 | **99** | | |
| G3. *MARYLAND ONLY: Medical Assistance? | 1 | 2 | **99** | | |
| G4. ALL STATES EXCEPT CALIFORNIA and MARYLAND: Medicaid? | 1 | 2 | **99** | | |
| G5. Private Health Insurance plan from employer or workplace? | 1 | 2 **(Skip to G6)** | | 1 | 2 |
| G6. Private Health Insurance plan purchased directly? | 1 | 2 **(Skip to G7)** | | 1 | 2 |
| G7. Private Health Insurance plan through a state or local government program or community program? | 1 | 2 **(Skip to G8)** | | 1 | 2 |
| G8. CHIP (Children's Health Insurance Program)? | 1 | 2 **(Skip to G9)** | | 1 | 2 |
| G9. Military Health Care/VA? | 1 | 2 **(Skip to G10)** | | 1 | 2 |
| G10. CHAMPUS or other veteran's health insurance? | 1 | 2 **(Skip to G11)** | | 1 | 2 |
| G11. Student Health Coverage? | 1 | 2 **(Skip to G12)** | | 1 | 2 |
| G12. State-Sponsored Health Plan? | 1 | 2 **(Skip to G13)** | | 1 | 2 |
| G13. Dental Insurance? | 1 | 2 | | | |
| G14. Vision Insurance? | 1 | 2 | | | |
| G15. Other types of health insurance? Specify _____ _____ _____ | 1 | 2 **(Skip to G16)** | | | |





Chronic Kidney Disease in Children

G16. Do any of these plans assist with prescriptions/medications?

Yes ..... 1
No ..... 2
Not applicable / No Insurance..... -1

G17. In the past year, has (*name of participant*) been without needed prescription medication due to cost?

Yes ..... 1
No ..... 2
Not applicable / No Insurance..... -1
Don't Know..... -8

G18. Does the participant's health insurance plan(s) pay for both doctor visits and hospital stays?

Yes ..... 1
No ..... 2
Don't Know..... -8

G19. In the past year, have you had difficulty filing claims and/or getting reimbursed for medical care?

Yes ..... 1
No ..... 2
Did not file any claims / No insurance -1
Don't Know..... -8

G20. In the past year, how much of a problem, if any, was it to get care for (name of participant) that you or a doctor believed necessary?

A big problem ..... 1
A small problem ..... 2
No problem..... 3
My child had not visits in the last year -1
Don't Know..... -8

G21. In the past year, how often did (*name of participant*) doctors or other health providers **listen carefully to you**?

Never..... 1
Sometimes..... 2
Usually..... 3
Always..... 4
My child had not visits in the last year -1
Don't Know..... -8

G22. In the past year, how often did (*name of participant*) doctors or other health providers **explain things** in a way you could understand?

Never..... 1
Sometimes..... 2
Usually..... 3
Always..... 4
My child had not visits in the last year -1
Don't Know..... -8

G23. In the past year, how often did (*name of participant*) doctors or other health providers show **respect for what you had to say**?

| | |
|---|---|
| Never | 1 |
| Sometimes | 2 |
| Usually | 3 |
| Always | 4 |
| My child had not visits in the last year | -1 |
| Don't Know | -8 |

G24. In the past year, how often did doctors or other health providers **spend enough time** with you and (*name of participant*)?

| | |
|---|---|
| Never | 1 |
| Sometimes | 2 |
| Usually | 3 |
| Always | 4 |
| My child had not visits in the last year | -1 |
| Don't Know | -8 |

We want to know your rating of all of (*name of participant*) health care in the last year from all **doctors and other health providers**. Use **any number from 0 to 10** where 0 is the worst health care possible, and 10 is the best health care possible.

G25. How would you rate all (*name of participant*) health care?

| | |
|---|---|
| 0 Worst health care possible | 0 |
| 1 | 1 |
| 2 | 2 |
| 3 | 3 |
| 4 | 4 |
| 5 | 5 |
| 6 | 6 |
| 7 | 7 |
| 8 | 8 |
| 9 | 9 |
| 10 | 10 |
| My child had not visits in the last year | -1 |
| Don't Know | -8 |

## SECTION H: RENAL REPLACEMENT THERAPY

H1. Have you ever discussed renal replacement therapy (i.e., dialysis or transplantation) with your nephrologist or health care provider?

Yes ..... 1
No ..... 2 **(END)**
Don't know..... -8 **(END)**

H2. In the past year, have you discussed renal replacement therapy with your nephrologist or health care provider?

Yes ..... 1
No ..... 2

a. Did you discuss renal replacement therapy **specifics** (i.e., modality, preference etc.) with your nephrologist?

Yes ..... 1
No ..... 2 **(END)**

H3. Was dialysis discussed?

Yes ..... 1
No ..... 2 **(skip to H5)**

H4. Which modality is preferred?

Hemodialysis ..... 1
Peritoneal dialysis..... 2
No Preference..... 3

H5. Was transplantation discussed?

Yes ..... 1
No ..... 2 **(END)**

H6. Which donor option(s) has/have been discussed?

**(Please circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | Yes | No | Don't Know |
|---|---|---|---|
| Living Donor..... | 1 | 2 | -8 |
| Deceased Donor..... | 1 | 2 | -8 |

H7. Has the participant been listed for deceased donor transplantation?

Yes ..... 1
No ..... 2 **(END)**

a. Date listed: ___ ___/ ___ ___/ ___ ___ ___ ___ ←**SITE SHOULD CONFIRM DATE**
M M / D D / Y Y Y Y



## TO BE COMPLETED BY CLINICAL SITE:

**DATE:** ___ ___/ ___ ___/ ___ ___ ___ ___ **INITIALS:** ___ ___ ___
M M / D D / Y Y Y Y

**ADMINISTRATION:** **(Circle "1", "2" or "3")**
1 = Interviewer Assisted
2 = Self-Administered
3 = Both

# FOLLOW-UP MEDICAL HISTORY (F14)

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: ___ ___

A3. FORM VERSION: 0 3 / 0 1 / 1 8

A4. DATE OF VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. SITE COORDINATOR'S INITIALS: ___ ___ ___

A6. Is this study visit an irregular (accelerated) visit?
Yes..... 1
No..... 2

A7. INDICATE PERSON COMPLETING THE FORM
Child/young adult..... 1
Parent or other adult..... 2
Both (Parent and Child/young adult) 3

***For each question, fill in the answer or circle the number that best matches the respondent's answer. Circle -8 for "Don't Know" responses. If a participant declines to answer a question, document -7 to the right of the response choice(s). For missing data, document -9 to the right of the response choice(s). Please document the reason for missing data (i.e., the question was accidentally skipped.)***

***Read each question and follow skip patterns as they appear on the form. Review the QxQ for detailed descriptions of questions.***



## INTRODUCTION TO PARTICIPANT:

**The following questions are about the participant's health history, including information about the current and past diseases that the participant may have had in life. Dates may be hard to remember. Please take as much time as you need so I can gather information that is as accurate as possible.**

**As with all study information, your responses will be kept strictly confidential, and the responses you provide will in no way affect the participant's clinical care. The first set of questions asks about the participant's kidney disease. Whenever the term "health care provider" is used, it means any doctor, nurse, physician assistant or nurse practitioner the child has ever seen. If you have trouble understanding anything, please feel free to ask for further clarification.**

## SECTION B: KIDNEY DISEASE

B1. In the past year, has *(name of participant)* been seen by a Urologist (adult or pediatric)?

Yes..... 1
No..... 2

**PROMPT: IF ANY OF B2 – B3 = YES, THEN COMPLETE THE MEDICAL ABSTRACTION TRACKING FORM (MAT).**

B2. In the past year, has (*name of participant*) had a urologic procedure, including surgery to treat his or her kidney problems?

Yes..... 1 → **(Complete MAT )**
No..... 2
Don't Know..... -8

B3. In the past year, has (*name of participant*) had a genetic test (i.e., Podocin or Nephrin) performed to help diagnose his or her kidney disease?

Yes..... 1 → **(Complete MAT )**
No..... 2
Don't Know..... -8

B4. In the past year, has a healthcare provider diagnosed (*name of participant*) with a kidney infection with a fever?

Yes..... 1
No..... 2 **(Skip to B5)**
Don't Know..... -8 **(Skip to B5)**

a. In the past year, how many times did he/she have a kidney infection with a fever?

___ ___ times
Don't Know..... -8

B5. Is participant a female?

Yes..... 1
No..... 2 **(Skip to C1)**

B6. In the past year, has (*name of participant*) started her menses (i.e. period)?

Yes..... 1
No..... 2 **(Skip to C1)**
Don't Know..... -8 **(Skip to C1)**

a. How old was she when she started her first period?

___ ___ years of age
Don't Know..... -8

## SECTION C: GENERAL MEDICAL HISTORY

**The next set of questions asks about diseases/illnesses that the participant had or developed in the past year.**

In the past year, has a doctor or any other healthcare professional told you that (*name of participant*) had or has developed any of the following diseases/illnesses?

**PROMPT: IF ANY OF C1 – C4 = YES, THEN COMPLETE THE MEDICAL ABSTRACTION TRACKING FORM (MAT).**

**(Please circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| C1. | GENERAL / METABOLIC DISEASE | | | |
| | a. Diabetes Mellitus (Sugar Diabetes, High Blood Sugar) | 1 | 2 | -8 |
| | b. Sickle Cell Disease | 1 | 2 | -8 |
| | c. Auto-immune Disease (Lupus, Rheumotid Arthritis) | 1 | 2 | -8 |
| C2. | CARDIOVASCULAR DISEASE | | | |
| | a. Heart Failure (Congestive heart failure) | 1 | 2 | -8 |
| | b. Stroke | 1 | 2 | -8 |
| | c. Left Ventricular Hypertrophy (LVH)/ Thickened Heart Muscle | 1 | 2 | -8 |
| C3. | LUNG DISEASE | | | |
| | a. Asthma | 1 | 2 | -8 |
| | b. Chronic Lung Disease | 1 | 2 | -8 |
| | c. Bronchopulmonary Dysplasia (BPD) | 1 | 2 | -8 |
| C4. | GENITOURINARY DISEASE | | | |
| | a. Urinary Tract Infections | 1 | 2 | -8 |
| | b. Blood in urine | 1 | 2 | -8 |
| | c. Protein in urine | 1 | 2 | -8 |
| | d. Passage of kidney stones | 1 | 2 | -8 |
| | e. Recurrent pain on urinating | 1 | 2 | -8 |
| C5. | GASTROINTESTINAL DISEASE | | | |
| | a. Gastroenteritis (stomach flu, food poisoning) | 1 | 2 | -8 |
| | b. Gastroesophageal Reflux (GERD) | 1 | 2 | -8 |
| | c. Gastrointestinal Ulcer | 1 | 2 | -8 |
| | d. Gastrointestinal Bleeding | 1 | 2 | -8 |
| | e. Liver Inflammation Non-Infectious | 1 | 2 | -8 |
| | f. Fatty Liver | 1 | 2 | -8 |
| | g. Irritable Bowel | 1 | 2 | -8 |
| | h. Encopresis (constipation) | 1 | 2 | -8 |

C6. In the past year, has a doctor or healthcare professional told you that (*name of participant*) has hypertension (high blood pressure)?

Yes..... 1 → Complete MAT
No..... 2 **(Skip to C7)**
Don't Know..... -8 **(Skip to C7)**

a. What is the status hypertension?

On meds but BP still high (Continued problem) 1
No longer hypertensive (Resolved problem) 2
On meds and BP controlled (Controlled w/ meds) 3

b. Was the hypertension diagnosed within the past year?

Yes..... 1
No..... 2
Don't Know..... -8

C7. In the past year, has a doctor or healthcare professional told you that (*name of participant*) has hepatitis?

Yes..... 1 → Complete MAT
No..... 2 **(Skip to C8)**
Don't Know..... -8 **(Skip to C8)**

a. Which of the following types of hepatitis does (name of participant) have?

| | Yes | No | Don't Know |
|---|---|---|---|
| Type A | 1 | 2 | -8 |
| Type B | 1 | 2 | -8 |
| Type C | 1 | 2 | -8 |
| Other type | 1 | 2 **(Skip to C7b)** | -8 **(Skip to C7b)** |

Specify: _____

b. Was the hepatitis diagnosed within the past year?

Yes..... 1
No..... 2
Don't Know..... -8

C8. In the past year, has a doctor or healthcare professional told you that (*name of participant*) has any other infection(s)?

Yes..... 1 → Complete MAT
No..... 2 **(Skip to C9)**
Don't Know..... -8 **(Skip to C9)**
Specify: _____

a. Was the infection diagnosed within the past year?

Yes..... 1
No..... 2
Don't Know..... -8

**(Please circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| C9. | CANCER | | | |
| a. | Leukemia | 1 | 2 | -8 |
| b. | Lymphoma | 1 | 2 | -8 |
| c. | Bone Cancer | 1 | 2 | -8 |
| d. | Liver Cancer | 1 | 2 | -8 |
| e. | Skin Cancer | 1 | 2 | -8 |
| f. | Soft Tissue Sarcoma | 1 | 2 | -8 |
| g. | Other | 1 | 2 **(Skip to C10)** | -8 **(Skip to C10)** |
| | Specify:_____ | | | |
| C10. | NEUROPSYCHIATRIC DISEASE | | | |
| a. | Attention Deficit Disorder (ADD) | 1 | 2 | -8 |
| b. | Attention Deficit Hyperactivity Disorder (ADHD) | 1 | 2 | -8 |
| c. | Depression | 1 | 2 | -8 |
| d. | Learning Disability other than ADD or ADHD | 1 | 2 | -8 |
| e. | Anxiety Disorder | 1 | 2 | -8 |
| f. | Other | 1 | 2 **(Skip to C11)** | -8 **(Skip to C11)** |
| | Specify:_____ | | | |

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| C11. | CHILDHOOD ILLNESSES | | | |
| a. | Measles | 1 | 2 | -8 |
| b. | German Measles | 1 | 2 | -8 |
| c. | Mumps | 1 | 2 | -8 |
| d. | Chickenpox | 1 | 2 | -8 |
| e. | Tuberculosis | 1 | 2 | -8 |
| f. | Whooping Cough | 1 | 2 | -8 |
| g. | Scarlet Fever | 1 | 2 | -8 |
| h. | Rheumatic Fever | 1 | 2 | -8 |
| i. | Diphtheria | 1 | 2 | -8 |
| j. | Meningitis | 1 | 2 | -8 |
| k. | Encephalitis | 1 | 2 | -8 |
| l. | Anemia | 1 | 2 | -8 |
| m | Fever above 104° for greater than 2 days | 1 | 2 | -8 |
| n. | Head injury including brain bleed | 1 | 2 | -8 |
| o. | Coma or loss of consciousness | 1 | 2 | -8 |
| p. | Other | 1 | 2 **(Skip to C12)** | -8 **(Skip to C12)** |
| | Specify:_____ | | | |

Please indicate whether (*name of participant*) has or has had any of the following problems.
**(Please circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | Yes | No | Don't Know |
|---|---|---|---|
| C12. NEUROLOGICAL | | | |
| a. Seizures/Convulsions | 1 | 2 | -8 |
| b. Speech Defects | 1 | 2 | -8 |
| c. Accident Prone | 1 | 2 | -8 |
| d. Bites Nails | 1 | 2 | -8 |
| e. Sucks Thumb | 1 | 2 | -8 |
| f. Grinds Teeth | 1 | 2 | -8 |
| g. Twitches/Tics | 1 | 2 | -8 |
| h. Bangs Head | 1 | 2 | -8 |
| i. Rocks Back and Forth | 1 | 2 | -8 |
| j. Bowel Movements in Bed/Pants | 1 | 2 | -8 |
| C13. HEARING | | | |
| a. Ear Infections | 1 | 2 | -8 |
| b. Hearing Problems | 1 | 2 | -8 |
| c. Ear Tubes | 1 | 2 | -8 |
| C14. VISION | | | |
| a. Vision Problems | 1 | 2 | -8 |
| b. Wears Glasses/Contacts | 1 | 2 | -8 |
| c. Color Blindness | 1 | 2 | -8 |

## SECTION D: ORTHOPEDIC HISTORY

**The next set of questions asks about any orthopedic injuries the participant may currently have or that the participant has had in the past year. Orthopedic injuries are injuries to the bones.**

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| D1. | In the past year, has a doctor or any other health professional told you that (name of participant) has had any broken bones? | 1 | 2 **(Skip to D2)** | -8 **(Skip to D2)** |

a. Please indicate which of the following bones (name of participant) has broken.
**(Please circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | | Yes | No | Don't Know |
|---|---|---|---|---|
| 1. | Back..... | 1 | 2 | -8 |
| 2. | Shoulder..... | 1 | 2 | -8 |
| 3. | Arm/Elbow..... | 1 | 2 | -8 |
| 4. | Wrist/Hand..... | 1 | 2 | -8 |
| 5. | Hip..... | 1 | 2 | -8 |
| 6. | Knee..... | 1 | 2 | -8 |
| 7. | Ankle..... | 1 | 2 | -8 |
| 8. | Foot..... | 1 | 2 | -8 |
| 9. | Leg..... | 1 | 2 | -8 |
| 10. | Fingers..... | 1 | 2 | -8 |
| 11. | Toes..... | 1 | 2 | -8 |
| 12. | Ribs..... | 1 | 2 | -8 |
| 13. | Collar Bone..... | 1 | 2 | -8 |

D2. Does (*name of participant*) have any bone disease in the hips?

Yes..... 1 → **(Complete MAT )**
No..... 2 **(Skip to F1)**
Don't Know..... -8 **(Skip to F1)**

a. Was the bone disease diagnosed within the past year?

Yes..... 1 → **(Complete MAT )**
No..... 2
Don't Know..... -8

## DELETED SECTION E

## SECTION F: HEALTHCARE UTILIZATION

**These questions ask about all the places the participant may have received care in the past year.**

F1. In the past year, where has (*name of participant*) gone to receive medical care? **(Please circle "Yes" or "No" for EACH of the following places.)**

Did (name of participant) go to…

| | | Yes | No |
|---|---|---|---|
| a. | A clinic or health care center | 1 | 2 |
| b. | A private doctor's office | 1 | 2 |
| c. | Hospital Outpatient Department | 1 | 2 |
| d. | The emergency room | 1 | 2 **(Skip to e)** |
| | 1. How many times has (name of participant) received care at the emergency room in the past year? ___ ___ | | |
| e. | Some other place | 1 | 2 **(Skip to F2)** |
| | 1. Please specify: _____ | | |

**These questions ask about the participant's use of health care. In this set of questions, the term "health care provider" means any doctor, nurse practitioner, or physician assistant you may go to for medical care.**

F2. In the past year, how many times did (*name of participant*) see a health care provider, not including this CKiD study visit or the visit at which you were screened for eligibility into the study? Include well child visits, sick visits and ER visits. **Do not include** times when (name of participant) was hospitalized overnight.

___ ___ times

Don't Know..... -8

F3. In the past year, when you or (*name of participant*) went for medical care, did he/she usually (more than half of the time) see the same health care provider or group of providers for his/her medical appointments?

Yes..... 1

No..... 2

Don't Know..... -8

# FOLLOW-UP MEDICAL HISTORY (F14)

**The next questions ask about hospitalizations. Being hospitalized includes staying overnight or being admitted for a procedure that was done in one day. Please include all medical and psychiatric hospitalizations in the past year. This does not include being treated in the emergency room and then released the same day.**

F4. In the past year, has (*name of participant*) been hospitalized (apart from when he or she was born)? Do not include overnight stays in the emergency room.

Yes ..... 1 → **(Complete MAT )**
No ..... 2 **(Skip to F5)**
Don't Know ..... -8 **(Skip to F5)**

a. How many different times was (*name of participant*) hospitalized in the past year?
___ ___ times

Don't Know ..... -8

**These questions ask some questions about care or social services that the participant may have received in the past year.**

F5. In the past year, has (*name of participant*) been seen by a social worker or a case manager to help him/her obtain services?

Yes ..... 1
No ..... 2

F6. In the past year, has (*name of participant*) received care or services from a psychologist, psychiatrist, psychiatric nurse, counselor, or other mental health professional?

Yes ..... 1
No ..... 2

F7. In the past year, has an agency assisted (*name of participant*) with food, such as food stamps or WIC, meals on wheels, food pantries, or arranged to have groceries delivered to your participant's parent/guardian's primary household (i.e., the home in which the participants lives at least half of the time or lived prior to living independently)?

Yes ..... 1
No ..... 2

F8. In the past year, has a social service agency helped you or (*name of participant*) find a place to live?

Yes ..... 1
No ..... 2

F9. In the past year, has (*name of participant*) received care from a dentist or dental hygienist?

Yes ..... 1
No ..... 2

F10. In the past year, has (*name of participant*) seen a nutritionist or a dietician?

Yes ..... 1
No ..... 2

## SECTION G: HEALTH INSURANCE

**These questions ask about the participant's health care coverage.**

G1. Does (*name of participant*) currently have any kind of health insurance or health care coverage? This includes both private and public insurance programs (e.g., Medicaid, SCHIP or MCHIP), dental insurance, and programs that help pay for medications.

Yes ..... 1 **(Skip to G1b)**
No ..... 2

G1a. How long has it been since (name of participant) last had ANY health insurance or coverage?

6 months or less ..... 1 **(skip to G14)**
More than 6 months, but no more than 1 yr ago..... 2 **(skip to G14)**
More than 1 year, but no more than 3 years ago..... 3 **(skip to G14)**
More than 3 years..... 4 **(skip to G14)**
Never had health insurance or coverage..... 5 **(skip to G14)**
Don't know..... -8 **(skip to G14)**

G1b. In the past year, was there any time when (name of participant) was not covered by ANY health insurance or coverage?

Yes ..... 1
No ..... 2 **(Skip to G2)**

G1c. In the past year, about how long was (name of participant) without ANY health insurance or coverage?

__ __ 1 = months 2 = weeks 3 = days

G1d. In the past year, was (name of participant) not covered by ANY insurance or coverage?

Yes ..... 1
No ..... 2

# FOLLOW-UP MEDICAL HISTORY (F14)

**INSTRUCTIONS: ASK QUESTIONS G2 - G15. IF THE RESPONSE IS YES, CIRCLE "1" AND ASK QUESTION "A" (FAR RIGHT COLUMN) UNLESS THE BOX IS SHADED.**

| Does (*name of participant*) currently have... | YES | NO | NA | **A.** Do you or your family members pay for any of the insurance premium? YES | NO |
|---|---|---|---|---|---|
| G2. *CALIFORNIA ONLY: Medi-CAL? | 1 | 2 | **99** | | |
| G3. *MARYLAND ONLY: Medical Assistance? | 1 | 2 | **99** | | |
| G4. ALL STATES EXCEPT CALIFORNIA and MARYLAND: Medicaid? | 1 | 2 | **99** | | |
| G5. Private Health Insurance plan from employer or workplace? | 1 | 2 **(Skip to G6)** | | 1 | 2 |
| G6. Private Health Insurance plan purchased directly? | 1 | 2 **(Skip to G7)** | | 1 | 2 |
| G7. Private Health Insurance plan through a state or local government program or community program? | 1 | 2 **(Skip to G8)** | | 1 | 2 |
| G8. CHIP (Children's Health Insurance Program)? | 1 | 2 **(Skip to G9)** | | 1 | 2 |
| G9. Military Health Care/VA? | 1 | 2 **(Skip to G10)** | | 1 | 2 |
| G10. CHAMPUS or other veteran's health insurance? | 1 | 2 **(Skip to G11)** | | 1 | 2 |
| G11. Student Health Coverage? | 1 | 2 **(Skip to G12)** | | 1 | 2 |
| G12. State-Sponsored Health Plan? | 1 | 2 **(Skip to G13)** | | 1 | 2 |
| G13. Dental Insurance? | 1 | 2 | | | |
| G14. Vision Insurance? | 1 | 2 | | | |
| G15. Other types of health insurance?<br>a. Specify _____<br>_____<br>_____ | 1 | 2 **(Skip to G16)** | | | |

G16. Do any of these plans assist with prescriptions/medications?

Yes ..... 1
No ..... 2
Not applicable / No Insurance..... -1

G17. In the past year, has (name of participant) been without needed prescription medication due to cost?

Yes ..... 1
No ..... 2
Not applicable / No Insurance..... -1
Don't Know..... -8

G18. Does the participant's health insurance plan(s) pay for both doctor visits and hospital stays?

Yes ..... 1
No ..... 2
Don't Know..... -8

G19. In the past year, have you had difficulty filing claims and/or getting reimbursed for medical care?

Yes ..... 1
No ..... 2
Did not file any claims / No insurance -1
Don't Know..... -8

G20. In the past year, how much of a problem, if any, was it to get care for (name of participant) that you or a doctor believed necessary?

A big problem ..... 1
A small problem ..... 2
No problem..... 3
My child had not visits in the last year -1
Don't Know..... -8

G21. In the past year, how often did (name of participant) doctors or other health providers **listen carefully to you**?

Never..... 1
Sometimes..... 2
Usually..... 3
Always..... 4
My child had not visits in the last year -1
Don't Know..... -8

G22. In the past year, how often did (name of participant) doctors or other health providers **explain things** in a way you could understand?

Never..... 1
Sometimes..... 2
Usually..... 3
Always..... 4
My child had not visits in the last year -1
Don't Know..... -8

G23. In the past year, how often did (name of participant) doctors or other health providers show **respect for what you had to say**?

| | |
|---|---|
| Never | 1 |
| Sometimes | 2 |
| Usually | 3 |
| Always | 4 |
| My child had not visits in the last year | -1 |
| Don't Know | -8 |

G24. In the past year, how often did doctors or other health providers **spend enough time** with you and (name of participant)?

| | |
|---|---|
| Never | 1 |
| Sometimes | 2 |
| Usually | 3 |
| Always | 4 |
| My child had not visits in the last year | -1 |
| Don't Know | -8 |

We want to know your rating of all of (name of participant) health care in the last year from all **doctors and other health providers**. Use **any number from 0 to 10** where 0 is the worst health care possible, and 10 is the best health care possible.

G25. How would you rate all (name of participant) health care?

| | |
|---|---|
| 0 Worst health care possible | 0 |
| 1 | 1 |
| 2 | 2 |
| 3 | 3 |
| 4 | 4 |
| 5 | 5 |
| 6 | 6 |
| 7 | 7 |
| 8 | 8 |
| 9 | 9 |
| 10 | 10 |
| My child had not visits in the last year | -1 |
| Don't Know | -8 |

## SECTION H: RENAL REPLACEMENT THERAPY

Deleted H1

H2. In the past year, have you discussed renal replacement therapy (i.e., dialysis or transplantation) with your nephrologist or health care provider?

Yes ..... 1
No ..... 2 **(END)**

a. Did you discuss renal replacement therapy **specifics** (i.e., modality, preference etc.) with your nephrologist?

Yes ..... 1
No ..... 2 **(END)**

H3. Was dialysis discussed?

Yes ..... 1
No ..... 2 **(skip to H5)**

H4. Which modality is preferred?

Hemodialysis ..... 1
Peritoneal dialysis..... 2
No Preference..... 3

H5. Was transplantation discussed?

Yes ..... 1
No ..... 2 **(END)**

H6. Which donor option(s) has/have been discussed?

**(Please circle "Yes", "No" or "Don't Know" for EACH of the following.)**

| | Yes | No | Don't Know |
|---|---|---|---|
| Living Donor..... | 1 | 2 | -8 |
| Deceased Donor..... | 1 | 2 | -8 |

H7. Has child been listed for deceased donor transplantation?

Yes ..... 1
No ..... 2 **(END)**

a. Date listed: ___ ___/ ___ ___/ ___ ___ ___ ___ ← **SITE SHOULD CONFIRM DATE**
M M / D D / Y Y Y Y

## TO BE COMPLETED BY CLINICAL SITE:

**DATE:** ___ ___/ ___ ___/ ___ ___ ___ ___
M M / D D / Y Y Y Y

**INITIALS:** ___ ___ ___

**ADMINISTRATION:**
**(Circle "1", "2" or "3")**

1 = Interviewer Assisted
2 = Self-Administered
3 = Both

Was the date listed on DECEASE DONOR LIST CONFIRMED by site:
1 = YES
2 = NO

# PHYSICAL EXAMINATION (PE)

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: ___ ___ ___

A3. FORM VERSION: 0 4 / 0 1 / 1 8

A4. DATE OF VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. EXAMINER'S INITIALS: ___ ___ ___

A6. Protocol type:
Regular Study Visit..... 0
Post-Dialysis Visit..... 1 **(Skip to B1)**
Post-Transplant Visit..... 2 **(Skip to B1)**

A7. Is this study visit an irregular (accelerated) visit?
Yes..... 1
No..... 2

A8. Is this a V1a or V1b study visit?
Yes..... 1
No..... 2 **(Skip to B1)**

A9. Has consent form been signed by young adult participant, parent or legal guardian?
Yes..... 1
No..... 2 **(STOP*)**

***WRITTEN CONSENT MUST BE OBTAINED**
**before performing any study related procedures or tasks.**

A10. Date parent, legal guardian or young adult participant signed consent form: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A11. Is documented assent required at your institution?
Yes..... 1
No..... 2 **(Skip to A13)**
N/A..... -1 **(Skip to A13)**

A12. Date of child assent: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A13. Has consent for genetic testing been obtained?
Yes..... 1
No..... 2

A14. Has consent to store biological specimen(s) been obtained?
Yes..... 1
No..... 2

**SECTIONS B – G can be completed by a Nurse or other Health Care Provider with CKiD Training**

# PHYSICAL EXAMINATION (PE)

## SECTION B: VITAL SIGNS

B1. a. Temperature:___ ___ ___ . ___

1 = °C Typical range: **36.1 – 38.3**

2 = °F Typical range: **94.5 – 100.6**

b. How was the temperature measured? **(Please circle the type of measurement.)**

Oral..... 1
Axillary..... 2
Tympanic..... 3

**DO NOT CALCULATE HEART RATE. ONLY ENTER NUMBER OF BEATS PER MINUTE**

B2. Pulse Measurement

a. Number of Heart Beats per minute: ___ ___ ___

B3. Local Clinical Blood Pressure (i.e. Dinamap): ___ ___ ___ / ___ ___ ___

B4. Respiratory Rate

a. Respirations per minute: ___ ___

## SECTION C: WEIGHT

C1. Child Weight **(If weight is measured in pounds (lbs), please convert to kilograms (kg).)**
1 lb = (1/2.2) kg **Example: 150 lbs** = 150/2.2 = 68.18 = **68.2 kg**

a. First Measurement: ___ ___ ___ . ___ **(kg)**

b. Second Measurement: ___ ___ ___ . ___ **(kg)**

i. Do the first and second measurements differ by more than 0.2 Kg?

Yes..... 1
No..... 2 **(Complete Specimen Collection Form)**

ii. Third Measurement: ___ ___ ___ . ___ **(kg)**

## SECTION D: HEIGHT, WAIST CIRCUMFERENCE and HIP CIRCUMFERENCE

D1. Child Length/Height

a. Device used to obtain length/height **(Please circle the device used.)**

Measuring table with firm block and moveable footboard..... 1
Wall mounted stadiometer..... 2

b. First Measurement: ___ ___ ___ . ___ (cm)

c. Second Measurement: ___ ___ ___ . ___ (cm)

i. Do the first and second measurements differ by more than 0.3 cm?

Yes..... 1
No..... 2 **(Skip to D3)**

ii. Third Measurement: ___ ___ ___ . ___ (cm)

**Deleted – Leg Length (Anterior Superior Iliac Spine to medial malleolus) questions**

D2 Is the participant less than 12 months old and/or unable to stand?

Yes..... 1 **(Skip to D5)**

No..... 2

D3. Child Waist Circumference

a. First Measurement: ___ ___ ___ . ___ (cm)

b. Second Measurement: ___ ___ ___ . ___ (cm)

i. Do the first and second measurements differ by more than 0.1 cm?

Yes..... 1

No..... 2 **(Skip to D4)**

ii. Third Measurement: ___ ___ ___ . ___ (cm)

D4. Child Hip Circumference

a. First Measurement: ___ ___ ___ . ___ (cm)

b. Second Measurement: ___ ___ ___ . ___ (cm)

i. Do the first and second measurements differ by more than 0.1 cm?

Yes..... 1

No..... 2 **(Skip to D5)**

ii. Third Measurement: ___ ___ ___ . ___ (cm)

D5. Parental Height

a. Was the biological mother's height taken at a previous study visit?

Yes..... 1 **(Skip to sub-question e)**

No..... 2

Don't know..... -8

b. Is the biological mother present during the study visit?

Yes..... 1

No ..... 3 **(Skip to sub-question e)**

c. Mother's First Measurement: ___ ___ ___ . ___ (cm)

d. Mother's Second Measurement: ___ ___ ___ . ___ (cm)

i. Do the first and second measurements differ by more than 0.3 cm?

Yes..... 1

No..... 2 **(Skip to sub-question e)**

ii. Mother's Third Measurement: ___ ___ ___ . ___ (cm)

e. Was the biological father's height taken at a previous study visit?
Yes..... 1 **(Skip to E1)**
No ..... 2
Don't know..... -8

f. Is the biological father present during the study visit?
Yes..... 1
No ..... 3 **(Skip to E1)**

g. Father's First Measurement: ___ ___ ___ . ___ (cm)

h. Father's Second Measurement: ___ ___ ___ . ___ (cm)

i. Do the first and second measurements differ by more than 0.3 cm?
Yes..... 1
No..... 2 **(Skip to E1)**

ii. Father's Third Measurement: ___ ___ ___ . ___ (cm)

## SECTION E: BLOOD PRESSURE USING MABIS-MEDIC-KIT ANEROID

**Some young children who are less than 5 years old may be irritable during the study visit. Therefore, it may be difficult to measure blood pressure while the child is awake. In such cases, blood pressure readings should be performed while the child is sleeping. It is important to accurately document if the participant is awake or sleeping. Please answer E1 appropriately.**

E1. Is/Was the blood pressure measurements obtained while the participant is awake?

Yes..... 1
No, participant was/is sleeping..... 2

Mid Arm Circumference

a. First Measurement: ___ ___ . ___(cm)

b. Second Measurement: ___ ___ . ___(cm)

i. Do the first and second measurements differ by more than 0.2 cm?
Yes..... 1
No..... 2 **(Skip to E2)**

ii. Third Measurement: ___ ___ . ___(cm)

**USE THE MID-ARM CIRCUMFERENCE MEASUREMENTS TO SELECT THE APPROPRIATE BP CUFF.**

E2. a. Cuff size used **(Please circle the cuff size used.)**
Infant (9.0 to 14.0 cm)..... 1
Child (>14.0 to 21.0 cm)..... 2
Adult (>21.0 cm to 29.0 cm) ..... 3
Large Adult (>29.0 cm to 40.0 cm) ..... 4
Thigh (>40.0 to 52.0cm) ..... 5

# PHYSICAL EXAMINATION (PE)

- **The cuff tubing should be attached to the Mabis Medic-Kit Aneroid sphygmomanometer.**
- **While palpating the radial pulse (at the wrist), observe sphygmomanometer and inflate the cuff rapidly to 60 mmHg and then slowly inflate in increments of 10 mmHg until the pulse is no longer felt.**
- **If the pulse is still felt, the cuff pressure should be increased until the pulse disappears. Either the first or the second of these procedures will identify the Observed Pulse Obliteration Pressure.**

b. Observed Pulse Obliteration Value ___ ___ ___

**ADD 30 mm Hg TO THE OBSERVED PULSE OBLITERATION VALUE TO CALCULATE THE PEAK INFLATION LEVEL**

c. Peak Inflation Pressure: ___ ___ ___

d. First Blood Pressure Reading: ___ ___ ___ / ___ ___ ___ ☐ 1) K4 ☐ 2) K5

**USE PARTICIPANT'S RIGHT ARM TO TAKE BP MEASUREMENT.**
**If right arm cannot be used (i.e., casting), then use left arm.**
**WAIT AT LEAST 30 SECONDS BETWEEN MEASUREMENTS.**
**AFTER FIRST AND SECOND BLOOD PRESSURE READING, RAISE CHILD'S ARM FOR 15 SECONDS (MAKE SURE THE CHILD IS NOT SUPPORTING THE ARM AT ALL.)**

**In some patients, the disappearance of sound, i.e. the fifth Korotkoff sound (K5), never occurs and beats can be heard during the entire deflation period. In these circumstances, the fourth Korotkoff sound (K4) should be used to determine the diastolic blood pressure. The fourth Korotkoff sound at the point during deflation where the quality of the sound changes dramatically (e.g. the quality of the beats become muffled.)**

e. Second Blood Pressure Reading: ___ ___ ___ / ___ ___ ___ ☐ 1) K4 ☐ 2) K5

f. Third Blood Pressure Reading: ___ ___ ___ / ___ ___ ___ ☐ 1) K4 ☐ 2) K5

g. Initials of Blood Pressure Reader: ___ ___ ___

# PHYSICAL EXAMINATION (PE)

## SECTION F: HEAD CIRCUMFERENCE

F1. Is the child less than 3 years old?

Yes..... 1

No..... 2 **(Skip to G1)**

F2. Head Circumference

a. First Measurement: ___ ___ ___(cm)

b. Second Measurement: ___ ___ ___(cm)

i. Do the first and second measurements differ by more than .3 cm?

Yes..... 1

No..... 2 **(Skip to G1)**

ii. Third Measurement: ___ ___ ___(cm)

## SECTION G: EDEMA

G1. Edema…..... ___

(Enter highest code. Code 0=none, 1=facial, 2=pretibial, 3=above knee, 4=presacral, 5=ascites, 6=anasarca)

G2. Is this a Visit 1b study visit or is the participant less than 12 months old?

Yes..... 1 **(Skip to Section I)**

No..... 2

**SECTION H should be completed by a Pediatrician, Nurse Practitioner, or Physician Assistant**

## SECTION H: TANNER STAGING

H1. a. Was the participant's previous CKiD tanner assessment "Adult (stage 5)"?

Yes..... 1 **(Skip to Section I)**

No..... 2

b. What is the participant's gender?

Male…..... 1 **(Skip to H4)**

Female…..... 2

**USE THE ASSESSMENT OF PUBERTAL STAGE LAMINATED CARD AND PICTURES TO ANSWER THE FOLLOWING QUESTIONS**

H2. If female participant, what is the developmental stage of her pubic hair?

Pre-pubertal..... 1

Sparse growth of slightly pigmented hair…..... 2

Darker, coarser, beginning to curl and spread over the symphysis…..... 3

Hair has adult characteristics but not adult distribution……..... 4

Adult…..... 5

H3. If female participant, what is the developmental stage of her breasts?

(Stage 1) Pre-pubertal..... 1 **(Skip to I1)**

(Stage 2) Budding..... 2 **(Skip to I1)**

(Stage 3) Small adult breasts..... 3 **(Skip to I1)**

(Stage 4) Areola and papilla form secondary mound..... 4 **(Skip to I1)**

(Stage 5) Adult breasts..... 5 **(Skip to I1)**

H4. If male participant, what is the developmental stage of his testes and scrotum?

Pre-pubertal..... 1

Enlargement of testes, scrotal reddening..... 2

Increasing length more than width of penis, further scrotal enlargement 3

Further penile enlargement, darkening of scrotal skin..... 4

Adult..... 5

H5. If male participant, what is the developmental stage of his pubic hair?

Pre-pubertal..... 1

Sparse growth of slightly pigmented hair..... 2

Darker, coarser, beginning to curl and spread over the symphysis..... 3

Hair has adult characteristics but not adult distribution..... 4

Adult..... 5

**USE THE ORCHIDOMETER (THE GREEN BEADS) PROVIDED BY CKiD.**

H6. If male participant, what is the testicular size per the orchidometer?

Bead 1, 2 or 3..... 1

Bead 4..... 2

Bead 5..... 3

Bead 6..... 4

Bead 8..... 5

Bead 10..... 6

Bead 12..... 7

Bead 15..... 8

Bead 20..... 9

Bead 25..... 10

# PHYSICAL EXAMINATION (PE)

## SECTION I: PROBLEMS

I1. Were there any sections of the physical exam form that were difficult to complete or not completed (i.e., participant was irritable and/or crying during blood pressure measurement and therefore, unable to obtain 1 of the 3 blood pressure measurements)?

Yes…… 1 **(Complete I2 on page 8)**

No…… 2 **(END HERE)**

I2. Please indicate the section of the physical exam form that was difficult to obtain data or not completed. Please circle yes or no to each section.

| | Yes | No | |
|---|---|---|---|
| a. **Section B:** Vital Signs…… | 1 | 2 | (**skip to b**) |
| i. Please specify:_____ | | | |
| b. **Section C:** Weight…… | 1 | 2 | (**skip to c**) |
| i. Please specify:_____ | | | |
| c. **Section D:** Height…… | 1 | 2 | (**skip to d**) |
| i. Please specify:_____ | | | |
| d. **Section D:** Waist Circumference …… | 1 | 2 | (**skip to e**) |
| i. Please specify:_____ | | | |
| e. **Section D:** Hip Circumference…… | 1 | 2 | (**skip to f**) |
| i. Please specify:_____ | | | |
| f. **Section E:** Blood Pressure Measure using Mabis Medic Kit…….... | 1 | 2 | (**skip to g**) |
| i. Please specify:_____ | | | |
| g. **Section F:** Head Circumference for children less than 3 years old | 1 | 2 **(skip to h)** | N/A (**skip to h**) |
| i. Please specify:_____ | | | |
| h. **Section G:** Edema…… | 1 | 2 | (**skip to i**) |
| i. Please specify:_____ | | | |
| i. **Section H:** Tanner Staging…… | 1 | 2 | (**END HERE**) |
| i. Please specify:_____ | | | |

# NUTRITIONAL ASSESSMENT (F15)

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: ___ ___

A3. FORM VERSION: 1 0 / 0 1 / 1 4a

A4. DATE OF VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. INTERVIEWER'S INITIALS: ___ ___ ___

A6. Is this study visit an irregular (accelerated) visit?
Yes..... 1
No..... 2

A7. INDICATE PERSON COMPLETING THE FORM
Child/Young Adult..... 1
Parent or other adult..... 2
Both (Parent and Child/Young Adult)..... 3

## SECTION B: NUTRITIONAL ASSESSMENT

**The following set of questions asks about the participant's appetite (or your appetite, if child/young adult participant is completing the form) and use of a nasogastric tube or gastrostomy tube. A nasogastric tube (NG tube) is a tube that is passed through the nose and down through the nasopharynx and esophagus into the stomach. A gastrostomy tube (GT) or button are tubes that directly enter the stomach.**

B1. During the past week, how would you rate (*name of participant*) appetite? Please circle one choice.

Very Good..... 1 **(Skip to B2)**
Good..... 2 **(Skip to B2)**
Fair..... 3
Poor..... 4
Very Poor..... 5

a. During the past week, did *(name of participant)* have an acute illness (i.e., cold, flu or tonsillitis) that altered *(name of participant)* normal appetite?

Yes..... 1
No..... 2 **(Skip to B2)**
Don't Know..... -8 **(Skip to B2)**

b. During the past week, on how many days was the child ill?

___ ___ days
Don't Know..... -8

B2. Does (*name of participant*) use a gastrostomy tube/button or Nasogastric tube (NG tube) for nutritional purposes?

Yes..... 1
No..... 2 **(Skip to B3)**
Don't Know..... -8 **(Skip to B3)**

a. In the past year, how many months has the gastrostomy tube/button or NG tube been used?

___ ___ months

Don't Know..... -8

B3. In a 24 hour time period, does (*name of participant*) take any nutritional supplement either by mouth, bottle or feeding tube to increase the caloric intake (*Excludes vitamins and minerals, See MEDS Form*)?

Yes..... 1
No..... 2 **(END FORM)**
Don't Know..... -8 **(END FORM)**

**Please use the following table to record the type and amount of any nutritional supplement or formula (to increase calories, protein or other nutrient intake) the child usually takes in a 24 hour period of time. This should include supplement or formula taken by mouth, bottle or feeding tube.**

***START F15s1***

| | a) Name of Formula or Supplement (Ex: Similac PM 60/40, Enfamil LIPIL, Suplena, PediaSure, Nepro, Ensure) | Amount of Formula (For pre-made liquid, use ounces; if made from powder, use teaspoons, tablespoons or cups) | | d) Additional ingredients/amounts* (Ex: 2 teaspoons Polycose, 1 Tablespoon MCT oil, 2 scoops Beneprotein) *If there are no additional ingredients/amount, record "N/A" |
|---|---|---|---|---|
| | | b) Amount | c) Unit | |
| B4. | | __ __ | Tsp……..…1<br>Tbsp……..…..2<br>Oz……...3<br>cup ……4 | |
| B5. | | __ __ | Tsp……..…1<br>Tbsp……..…..2<br>Oz……...3<br>cup ……4 | |

***END F15s1***

## Chronic Kidney Disease in Children (CKiD)

### SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: ___ ___

A3. FORM VERSION: 1 0 / 0 1 / 1 4

A4. DATE OF VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. INTERVIEWER'S INITIALS: ___ ___ ___

A6. Is this study visit an irregular (accelerated) visit?
Yes..... 1
No..... 2

A7. Indicate the person completing the form?
Participant..... 1
Parent..... 2
Both..... 3

## SECTION B: SEDENTARY ACTIVITY

B1. Over the **past 30 days**, on average how many hours per day did *(name of participant)* sit and watch TV or videos?

| | |
|---|---|
| None, does not watch TV or videos…….…... | 1 |
| Less than 1 hour per day..... | 2 |
| 1 hour per day..... | 3 |
| 2 hours per day..... | 4 |
| 3 hours per day..... | 5 |
| 4 hours per day..... | 6 |
| 5 or more hours per day..... | 7 |
| Don't know..... | -8 |

B2. Over the **past 30 days**, on average how many hours per day did *(name of participant)* use a computer or play computer games/internet outside of school? Include Facebook or other social networking tools, YouTube, smartphone, Playstation, Nintendo DS, smartphone, iPad or other tablet, iPod.

| | |
|---|---|
| None, does not use a computer or play computer games | 1 |
| Less than 1 hour per day..... | 2 |
| 1 hour per day..... | 3 |
| 2 hours per day..... | 4 |
| 3 hours per day..... | 5 |
| 4 hours per day..... | 6 |
| 5 or more hours per day..... | 7 |
| Don't know..... | -8 |

B3. How much time does *(name of participant)* usually spend sitting on a typical day? This includes sitting at work/school, at home, getting to and from places, or with friends, including time spent sitting at a desk, traveling in a car or bus, reading, playing cards, watching television, or using a computer. **Do not include time spent sleeping.**

**___ hr ___ ___ mins**

## OVERALL PHYSICAL ACTIVITY (F17)

### SECTION C: OVERALL ACTIVITY LEVEL

C1. During the **past 7 days**, on how many days was *(name of participant)* physically active for a total of **at least 60 minutes per day**? Add up all the time *(name of participant)* spent in any kind of physical activity that increased {his/her} heart rate and made {him/her} breathe hard some of the time.

| | |
|---|---|
| 0 days..... | 1 |
| 1 day..... | 2 |
| 2 days..... | 3 |
| 3 days..... | 4 |
| 4 days..... | 5 |
| 5 days..... | 6 |
| 6 days..... | 7 |
| 7 days..... | 8 |
| Don't know..... | -8 |

C2. On how many of the **past 7 days** did *(name of participant)* exercise or participate in physical activity **for at least 20 minutes** that made {him/her} sweat and breathe hard, such as basketball, soccer, running, swimming laps, fast bicycling, fast dancing, or similar aerobic activities?

____ ____ days

C3. On how many of the **past 7 days** did *(name of participant)* participate in physical activity for **at least 30 minutes** that **did not** make {him/her} sweat and breathe hard, such as fast walking, slow bicycling, skating, pushing a lawn mower or mopping floors?

____ ____ days

### SECTION D: PAID OR UNPAID WORK ACTIVITY

**Think about the time that *(name of participant)* spends doing work. Think of work as the things that *(name of participant)* does such as paid or unpaid work, household chores and/or yard work.**

**Vigorous-intensity activity causes large increases in breathing or heart rate and is done for at <u>least 10 minutes continuously.</u>**

D1. Does *(name of participant)* work involve **vigorous-intensity** activity that causes large increases in breathing or heart rate like carrying or lifting heavy loads for **at least 10 minutes continuously**?

| | |
|---|---|
| Yes..... | 1 |
| No..... | 2 **(Skip to D4)** |
| Don't know..... | -8 **(Skip to D4)** |

D2. In a **typical week**, on how many days does *(name of participant)* do **vigorous-intensity** activities as part of {his/her} work?

____ ____ days

D3. How much time does *(name of participant)* spend doing **vigorous-intensity** activities at work on a typical day?

____ ____ 1 = minutes
2 = hours

**Moderate-intensity sports, fitness or recreational activities cause small increases in breathing or heart rate and is done for at <u>least 10 minutes continuously</u>.**

D4. Does *(name of participant)* work/chores involve **moderate-intensity** activity that causes small increases in breathing or heart rate such as brisk walking or carrying light loads for **at least 10 minutes continuously**?

Yes**.....** 1
No**.....** 2 **(Skip to E1)**
Don't know**.....** -8 **(Skip to E1)**

D5. In a **typical week**, on how many days does *(name of participant)* do **moderate-intensity** activities as part of their work/chore?

____ ____ days

D6. How much time does *(name of participant)* spend doing **moderate-intensity** activities at work on a **typical day**?

____ ____ 1 = minutes
2 = hours

## SECTION E: TRAVELING AND COMMUTING

**The next questions exclude the physical activity of work (including household chores) that has already been mentioned. Now I would like to ask about the usual way that *(name of participant)* travels to and from places. For example, travel to school, for shopping, to work.**

E1. Does *(name of participant)* walk or bicycle for **at least 10 minutes continuously** to get to and from places?

Yes**.....** 1
No**.....** 2 **(Skip to F1)**
Don't know**.....** -8 **(Skip to F1)**

E2. In a **typical week**, on how many days does *(name of participant)* walk or bicycle for **at least 10 minutes continuously** to get to and from places?

____ ____ days

E3. How much time does *(name of participant)* spend walking or bicycling for travel on a **typical day**?

____ ____ 1 = minutes
2 = hours

## SECTION F: SCHOOL, SPORTS AND RECREATIONAL ACTIVITY

**The next questions exclude the work and transportation activities that have already been mentioned. Now I would like to ask about school, sports, fitness and recreational activities.**

F1. In an **average week** when *(name of participant)* is in school, on how many days does {he/she} go to physical education (PE) classes?

____ ____ days **(If "0", Skip to F3)**

F2. During an average physical education (PE) class, how many minutes does *(name of participant)* spend actually exercising or playing sports?

Less than 10 minutes per day..... 1
10 to 20 minutes per day..... 2
21 to 30 minutes per day..... 3
31 to 40 minutes per day..... 4
41 to 50 minutes per day..... 5
51 to 60 minutes per day..... 6
More than 60 minutes per day..... 7
Don't know..... -8

F3. During the **past 12 months**, on how many sports teams did *(name of participant)* play? (Include any teams run by {his/her} school or community groups.)

____ ____ teams

**Vigorous-intensity activity causes large increases in breathing or heart rate and is done for at <u>least 10 minutes continuously.</u>**

F4. Does *(name of participant)* do any **vigorous-intensity** sports, fitness, or recreational activities that cause large increases in breathing or heart rate like running or basketball for **at least 10 minutes continuously**?

Yes..... 1
No..... 2 **(Skip to F7)**
Don't know..... -8 **(Skip to F7)**

F5. In a **typical week**, on how many days does *(name of participant)* do **vigorous-intensity** sports, fitness or recreational activities?

____ ____ days

F6. How much time does *(name of participant)* spend doing **vigorous–intensity** sports, fitness or recreational activities on a **typical day**?

____ ____ 1 = minutes
2 = hours

## OVERALL PHYSICAL ACTIVITY (F17)

**Moderate-intensity sports, fitness or recreational activities cause small increases in breathing or heart rate and is done for at <u>least 10 minutes continuously</u>.**

F7. Does *(name of participant)* do any **moderate-intensity** sports, fitness, or recreational activities that cause a small increase in breathing or heart rate such as brisk walking, bicycling for pleasure, swimming or golf for **at least 10 minutes continuously**?

Yes**.....** 1
No**.....** 2 **(END FORM)**
Don't know**.....** -8 **(END FORM)**

F8. In a **typical week**, on how many days does *(name of participant)* do **moderate-intensity** sports, fitness or recreational activities?

____ ____ days

F9. How much time does *(name of participant)* spend doing **moderate-intensity** sports, fitness or recreational activities on a typical day?

____ ____ 1 = minutes
2 = hours

# HAND GRIP TEST (F19)

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: ___ ___

A3. FORM VERSION: 1 0 / 0 1 / 1 4

A4. DATE OF VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___

M M D D Y Y Y Y

A5. FORM COMPLETED BY (INITIALS): ___ ___ ___

**Instructions:**

The purpose of this form is to assess the participant's grip strength. Participants should complete this form if they:

- are six (6) years old or older at the time of the study visit
- have at least one hand without visible limitations (i.e., wearing cast/bandage, missing digits, paralysis)
- have not had surgery performed on either hand within the past three (3) months
- are not using a wheelchair (i.e., not wheelchair bound)

The following procedure should be followed:

1. Read pre-test script and administer Pre-Hand-Grip Test questionnaire
2. Ask participant to remove hand jewelry, adjust dynamometer for grip size; administer practice test
3. Administer Hand-Grip Test according to protocol, 3 times on each hand if alternating between hands or 6

A6. a. Is participant at least **6 years** of age?

Yes..... 1
No..... 2 → **(END FORM)**

b. Are there **any visible limitations** to the participant's hands (missing arm, hand, or thumb; hand paralysis; wearing a cast on wrist or hand; most of hand covered by bandages; missing fingers other than thumb or broken fingers)?

No visible limitations..... 0
Visible limitation to **right** hand..... 1
Visible limitation to **left** hand..... 2
Visible limitation to **both** hands..... 3 → **(END FORM)**

c. Has the participant had **hand surgery** in the past 3 months?

No surgery to hands in the last 3 months..... 0
Yes, surgery to **right** hand in the last 3 months..... 1
Yes, surgery to **left** hand in the last 3 months..... 2
Yes, surgery to **both** hands in the last 3 months..... 3 → **(END FORM)**





Chronic Kidney Disease in Children

d. Does the participant have at least **one hand** without any visible limitations and in which no hand surgery has been performed in the last 3 months? (**Only complete grip strength of hands with no visible limitation and no surgery in the last 3 months)**
Yes..... 1
No..... 2 → **(END FORM)**

e. Is the participant using a wheelchair?
Yes..... 1 → **(END FORM)**
No..... 2

A7. Did the participant complete the Hand Grip Test?
Yes..... 1
No..... 2 → **(END FORM)**

Read the **pre-test** script to the participants:

***In this exam, we want to get some information about your muscle strength. We will be asking you to squeeze as hard as possible with each of your hands or at least one of your hands. I will explain this in more detail in a few minutes but first I want to ask you a few questions.***

## SECTION B: PRE-HAND GRIP TEST QUESTIONNAIRE

B1. a. Have you **ever** had surgery on your hands or wrists for **arthritis** or **carpal tunnel syndrome**?
Yes..... 1
No..... 2 → **(Skip to B2)**
Don't Know..... -8 → **(Skip to B2)**

b. Which hand or wrist was the surgery on?
Right hand/wrist..... 1
Left hand/wrist..... 2
Both hands/wrist..... 3
Don't Know..... -8

B2. a. Have you had any pain, aching or stiffness in your hands in the **past 7 days**?
Yes..... 1
No..... 2 → **(Skip to B3)**

b. Is the pain, aching or stiffness in your hand(s) caused by **arthritis, tendonitis,** or **carpal tunnel syndrome**? (Choose only one response.)
No, pain is not caused by arthritis, tendonitis or carpal tunnel syndrome..... 0
Yes, pain in **right** hand is caused by arthritis, tendonitis or carpal tunnel syndrome..... 1
Yes, pain in **left** hand is caused by arthritis, tendonitis or carpal tunnel syndrome..... 2
Yes, pain in **both** hands is caused by arthritis, tendonitis or carpal tunnel syndrome…. 3
Don't Know..... -8

c. Has the pain, aching or stiffness in your hand(s) gotten worse in the past 7 days? (Choose only one response.)
No pain has not gotten worse..... 0
Yes, pain has gotten worse in the **right** hand.... 1
Yes, pain has gotten worse in the **left** hand..... 2
Yes, pain has gotten worse in **both** hands..... 3
Don't Know..... -8

B3. Are you right-handed, left-handed, or do you use both hands equally?
Right-handed..... 1
Left-handed..... 2
Use both hands equally..... 3
Don't Know..... -8

1. **Instruct the participant to remove all hand and wrist jewelry.**
2. **Have the participant complete two warm-up exercises on the hand or hands to be tested**
   a. **Shake both hands three (3) times**
   b. **Bend and stretch all fingers three (3) times**

**FOLLOW STEPS 2 – 7 and FIGURES 1.1 – 1.4 of the CHEAT SHEET for details on ADJUSTING GRIP SIZE and obtaining a 90° angle).**

**Also refer to Section 29 of the Manual of Procedures (MOP) for details.**

Introduce the grip size adjustment by reading the following script:

***"Next, I am going to adjust this device to fit your hand(s). Please hold this with your (right/left hand)."***

B4. Was the participant able to achieve a 90° angle with the **right** index finger?
Yes..... 1 → **(Skip to B5)**
No..... 2
Don't Know..... -8 → **(Skip to B5)**
1. Please specify, reason: _____

B5. Was the participant able to achieve a 90° angle with the **left** index finger?
Yes..... 1 → **(PRE-TEST ENDS HERE)**
No..... 2
Don't Know..... -8 → **(PRE-TEST ENDS HERE)**
1. Please specify, reason: _____

**STOP HERE AND PREPARE TO ADMINISTER THE HAND GRIP.**
**FOLLOW STEPS 9 – 14 and FIGURES 1.5 – 1.6 in the CHEAT SHEET for details on performing the demo and practice trial.**
**STEP 9 BEGINS WITH READING THE SCRIPT.**

**Also refer to Section 29 of the MOP for details.**

Read the script to the participant and demonstrate the grip test:

***"For the test, I will ask you to squeeze this hand grip as hard as you can. You will stand with your feet hip width apart and your toes pointing forward like this. You will position your hand so that it's not touching your body and squeeze the handle. I want you to stand tall and try not to lean when you squeeze. You will take a breath in, then blow out while you squeeze. You will squeeze as hard as you can until you can't squeeze any harder. Like this.***

*(Do the squeeze demo)*

*If testing both hands, say:* ***We will test each hand 3 times.***

*If testing same hand, say:* ***We will test your hand 6 times."***

**PERFORM THE DEMO.**

Instruct the participant to do the practice trial by reading the script below:

***"Now try it once just to get the feel of it. For this practice, just squeeze gently. Ready, take a breath in, let it out, squeeze gently."***



## SECTION C: HAND GRIP PREPARATION

C1. a. Are both hands being tested? (only test hands without visible limitations, and no surgery in the past 3 months)
Yes..... 1
No..... 2

b. Which hand was used for the Practice Test*?
*Participant only has to perform one practice test. However, additional practice test can be performed if needed. Use the same hand to perform all practice tests.
Right hand..... 1
Left hand..... 2

c. Was the dynamometer cleared by pressing "ON/Clear"?
Yes..... 1
No..... 2

# HAND GRIP TEST (F19)

**Now the participant is ready to do the hand grip strength test.**
**FOLLOW STEPS 16 – 20 IN THE CHEAT SHEET and FIGURES 1.5 – 1.6 for details on administering the grip strength test.**

**Also refer to Section 29 of the MOP for details.**

## SECTION D: HAND GRIP TEST

Start the stopwatch after each test. The stopwatch is used to ensure that the participant waits at **least 60 seconds between each test**. After appropriate time has elapsed, reset the stopwatch to zero (i.e., 00:00). If using two hands for the test, then have the participant start the test with the opposite hand than was used during the practice test. Note that "maximal" effort is define as when the hand slightly shakes.

**Remember to press "ON/Clear" before starting each test.**

| | Grip Test | (i) Hand | (ii) Dynamometer Reading | (iii) Effort |
|---|---|---|---|---|
| D1. | Grip Test #1<br>Comments: | 1 = right<br>2 = left | ___ ___ . ___ | 1 = maximal<br>2 = questionable |
| D2. | Grip Test #2<br>Comments: | 1 = right<br>2 = left | ___ ___ . ___ | 1 = maximal<br>2 = questionable |
| D3. | Grip Test #3<br>Comments: | 1 = right<br>2 = left | ___ ___ . ___ | 1 = maximal<br>2 = questionable |
| D4. | Grip Test #4<br>Comments: | 1 = right<br>2 = left | ___ ___ . ___ | 1 = maximal<br>2 = questionable |
| D5. | Grip Test #5<br>Comments: | 1 = right<br>2 = left | ___ ___ . ___ | 1 = maximal<br>2 = questionable |
| D6. | Grip Test #6<br>Comments: | 1 = right<br>2 = left | ___ ___ . ___ | 1 = maximal<br>2 = questionable |





Chronic Kidney Disease in Children

# MEDICATION AND SUPPLEMENT INVENTORY (MEDS)

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: ___ ___

A3. FORM VERSION: 1 0 / 0 1 / 1 2b

A4. DATE OF VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. INTERVIEWER'S INITIALS: ___ ___ ___

A6. Who completed this form?

| | |
|---|---|
| Child/young adult ..... | 1 |
| Parent..... | 2 |
| Both (Parent and Child/young adult) | 3 |
| Other..... | 4 |

A7. Has your child taken any medications in the last 30 days?

| | | |
|---|---|---|
| Yes..... | 1 → | **(If medication is in the form of a Pill/Tablet/Patch/Powder skip to A9 on page 2, otherwise skip to A9 on page 3)** |
| No..... | 2 | |

A8. Were there any medications that your child was supposed to take but did not take in the past 30 days?

| | | |
|---|---|---|
| Yes..... | 1 → | **(If medication is in the form of a Pill/Tablet/Patch/Powder continue to A9 on page 2, otherwise go to A9 on page 3)** |
| No..... | 2 | **(END FORM HERE)** |

**Instructions:** The family should have brought the bottles/packages of all medications ***and any herbal remedies, health supplements, vitamins, etc.*** that the child has taken ***in the last 30 days prior*** to the baseline study visit**.** The interviewer should confirm that all medications are present, and examine the medication and supplement packages to complete this form.

Please **complete Section B for each of the medications the participant has taken, or was supposed to take in the last 30 days**.

If medication is in the form of a Pill, Tablet, Patch, or Powder complete **Question A9 and Section B on page 2**.

If medication is in the form of Drops, Inhaler/Spray, Nebulizer, Rectal Formulation or Liquid (syrup, gel, cream, lotion, injection), complete **Question A9 on page 3 and Section B on page 3**.

Only one medication may be recorded on each page. Therefore, additional copies are provided in the binder. Please note that sites may have to make more copies, as needed.

# MEDICATION AND SUPPLEMENT INVENTORY (MEDS)

## Pill/Tablet/Patch/Powder

**A9. What is the DRUG's form?** Pill/Tablet/Patch/Powder…. 1 *(If drug form is NOT a Pill/Tablet/Patch/Powder, go to page 3)*

Section B: Pill/Tablet/Patch/Powder

| | B1a. **Medication** (Brand Name and/or Generic) | B1b. **Drug Code:** (see medication coding sheets provided in the binder) | B1c. How is the drug **taken**[a]? (see **ADMINISTRATION** codes on page 4) | B2. **Individual Dose** | B3. **Units**[b] (see **UNITS** codes on page 4) | B5. What is the **frequency**[c] that drug suppose be taken? (see **FREQUENCY** codes on page 4) |
|---|---|---|---|---|---|---|
| **1** | | __ __ -- __ __ -- __ __ | __ __ | __ __ __ . __ __ | __ __ | __ __ |

| B6. Is (DRUG) a prescribed medication? | B7. How many times did (name of participant) take prescribed medication **in the past 30 days**? | B8. Has (name of participant) missed taking (DRUG) **in the past 30 days**? | B9. Has (DRUG) been taken as prescribed in **the past 7 days**? |
|---|---|---|---|
| Yes.....1<br>No..... 2 (END) | __ __ __ | Yes..... 1<br>No..... 2 (END) | Yes..... 1(END)<br>No.....2 |

Section C: Medication Adherence for Prescribed Medication

[d] **BOTHER: 1 = Never 2 = Sometimes 3 = Often 4 = Always** [e] **RATE: 1 = Very Well 2 = Somewhat 3 = Not at all -8 = Don't know**

| C2. **In the past 7 days**, how many **times** was drug missed? **(If "0" skip to C3)** | C2a. For the times when missed, how many times was this due to the child refusing to take medication? | C3. Does drug bother[d] child? (see codes listed above) | C4. How well[e] do you think the drug helps? (see codes listed above) | C5. Please answer the following questions by responding "never", "sometimes" or "a lot" for EACH statement. Remember your answers will be kept private. 0 = Never (N), 1 = Sometimes (S), 2 = A lot (A) | | | |
|---|---|---|---|---|---|---|---|
| __ __ | __ __ | __ | __ | a. The medication causes side effects. | 0 | 1 | 2 |
| | | | | b. It is hard to remember to give (name of participant) the (DRUG). | 0 | 1 | 2 |
| | | | | c. It is hard to get to the pharmacy to pick up the (DRUG). | 0 | 1 | 2 |
| | | | | d. It is hard to open the (DRUG) container. | 0 | 1 | 2 |
| | | | | e. It is hard to get the (DRUG) refill on time. | 0 | 1 | 2 |
| | | | | f. It is hard to remember to give (name of participant) the (DRUG) on weekends. | 0 | 1 | 2 |
| | | | | g. It is hard to pay for the (DRUG). | 0 | 1 | 2 |
| | | | | h. The (DRUG) tastes bad. | 0 | 1 | 2 |
| | | | | i. It hurts/is painful to take (DRUG). | 0 | 1 | 2 |
| | | | | j. Other reason, specify: _____ | 0 | 1 | 2 |

# MEDICATION AND SUPPLEMENT INVENTORY (MEDS)

## Drop/Inhaler/Nebulizer/Rectal Formulation/Liquid (syrup, gel, cream, lotion, injection)

**A9. What is the DRUG's form?** Drop…….. 2 Inhaler/Spray… 3 (Skip to **B1a)** Liquid (syrup/gel/cream/lotion/injections)…5 (Skip to **B1a**)
Nebulizer..... 4 (Skip to **B1a**) Rectal Formulation……..…..6 (Skip to **B1a**)

**A9a. If drops, where is dose delivered?**

Right ……....1 Left ……..2 Both ……..3 Other……99

### Section B: Drop/Inhaler/Nebulizer/Rectal Formulation/Liquid (syrup, gel, cream, lotion, injection)

| | B1a. **Medication** (Brand Name and/or Generic) | B1b. **Drug Code:** (see medication coding sheets provided in binder) | B1c. How is the drug **taken**[a]? (see **ADMINISTRATION** codes on page 4) | B1e. **Volume of the dose** (or number of drops/puffs /nebulizer treatment/suppository) and indicated the units[b1] (**see VOLUME UNITS** codes on page 4) | B1f. **Concentration** This is a measurement unit per a specific volume. (Refer to the medication label) Indicate the **measuring unit**[b2] in the 1st column and the **volume unit**[b3] in the 2nd column. (see **CONCENTRATION UNITS** codes on page 4) | | B5. What is the **frequency**[c] that drug suppose be taken? (see **FREQUENCY** codes on page 4) |
|---|---|---|---|---|---|---|---|
| **1** | | __ __ - __ __ - __ __ | __ __ | __ __ __ . __ __ *Unit: ____ ____* | __ __ __ __ . __ __ __ *Unit: ____ ____* | __ __ __ *Unit: ____ ___* | __ __ |

| B6. Is (DRUG) a prescribed medication? | B7. How many times did (name of participant) take prescribed medication **in the past 30 days**? | B8. Has (name of participant) missed taking (DRUG) **in the past 30 days**? | B9. Has (DRUG) been taken as prescribed in **the past 7 days**? |
|---|---|---|---|
| Yes.....1<br>No..... 2 (END) | __ __ __ | Yes..... 1<br>No..... 2 (END) | Yes..... 1(END)<br>No.....2 |

### Section C: Medication Adherence for Prescribed Medication

[d] **BOTHER: 1 = Never 2 = Sometimes 3 = Often 4 = Always** | [e] **RATE: 1 = Very Well 2 = Somewhat 3 = Not at all -8 = Don't know**

| C2. **In the past 7 days**, how many **times** was drug missed? **(If "0" skip to C3)** | C2a. For the times when missed, how many times was this due to the child refusing to take medication? | C3. Does drug bother[d] child? (see codes listed above) | C4. How well[e] do you think the drug helps? (see codes listed above) | C5. Please answer the following questions by responding "never", "sometimes" or "a lot" for EACH statement. Remember your answers will be kept private. 0 = Never (N), 1 = Sometimes (S), 2 = A lot (A) | | | |
|---|---|---|---|---|---|---|---|
| __ __ | __ __ | __ __ | __ | a. The medication causes side effects. | 0 | 1 | 2 |
| | | | | b. It is hard to remember to give (name of participant) the (DRUG). | 0 | 1 | 2 |
| | | | | c. It is hard to get to the pharmacy to pick up the (DRUG). | 0 | 1 | 2 |
| | | | | d. It is hard to open the (DRUG) container. | 0 | 1 | 2 |
| | | | | e. It is hard to get the (DRUG) refill on time. | 0 | 1 | 2 |
| | | | | f. It is hard to remember to give (name of participant) the (DRUG) on weekends. | 0 | 1 | 2 |
| | | | | g. It is hard to pay for the (DRUG). | 0 | 1 | 2 |
| | | | | h. The (DRUG) tastes bad. | 0 | 1 | 2 |
| | | | | i. It hurts/is painful to take (DRUG). | 0 | 1 | 2 |
| | | | | j. Other reason, specify: _____ | 0 | 1 | 2 |

# MEDICATION AND SUPPLEMENT INVENTORY (MEDS)

## CODES AND EXAMPLES

**Codes for page 2 medication that is in the form of a Pill/Tablet/Patch/Powder**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **[a] ADMINISTRATION Code:** | **1 = oral** | **3 = inhalation** | **4 = intranasal** | **10 = transdermal** | **Injection:** | **5 = intravenous** | **12 = intramuscular** |
| **97 = other** | **6 = nasogastric** | **7 = per rectal** | **9 = sublingual** | **11 = topical** | | **8 = subcutaneous** | **13 = intradermal** |

**[b] UNITS Code:** **1 = mg** **2 = mcg** **9 = vitamins** **10 = g** **11 = %** **98 = other** **Specify:**_____

| | | | | |
|---|---|---|---|---|
| **[c] FREQUENCY Code:** | **3 = q8 / tid (every 8 hours or 3 times/day)** | **6 = qod (every other day)** | **7 = qweek (every week)** | **13 = qmonth (every month)** |
| **1 = q4 (every 4 hours)** | **4 = q12 / bid (every 12 hours or twice/day)** | **10 = triweek (3 times/week)** | **11 = q2week (every 2 weeks)** | **9 = PRN (as needed)** |
| **2 = q6 (every 6 hours)** | **5 = q24 / qday (every day or once/day)** | **14 = biweek (2 times/week)** | **12 = q3week (ever 3 weeks)** | **8 = other: Specify Other:** _____ |

| | B1a. **Medication** (Brand Name and/or Generic) | B1b. **Drug Code:** | B1c. How is the drug **taken[a]**? (see **ADMINISTRATION** codes) | B2. **Individual Dose** | B3. **Units[b]** (see **UNITS** codes) | B5. What is the **frequency[c]** that drug suppose be taken? (see **FREQUENCY** codes) |
|---|---|---|---|---|---|---|
| *0* | **Tums Ultra** | ***1 2 - 0 1 - 0 0*** | ___ ***1*** | ***1 0 0 0 . 0 0*** | ___ ***1*** | ___ ***3*** |

**Codes for page 3 medication that is in the form of a Drop/Inhale/Nebulizer/ Rectal Formulation/ Liquid (syrup, gel, cream, lotion, injection)**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **[a] ADMINISTRATION Code:** | **1 = oral** | **3 = inhalation** | **4 = intranasal** | **10 = transdermal** | **Injection:** | **5 = intravenous** | **12 = intramuscular** |
| **99 = other** | **6 = nasogastric** | **7 = per rectal** | **9 = sublingual** | **11 = topical** | | **8 = subcutaneous** | **13 = intradermal** |

**[b1] Volume UNITS Code:** **1 = ml/cc** **2 = L** **3 = drop** **4 =puff/nebulizer** **5 = suppository** **6 = grams** **-1 = N/A (topical cream)** **99 = Other** **Specify:**_____

**[b2] Concentration UNITS (1st Column):** **1 = mcg** **2 = mg** **3 = g** **4 = %** **5 = units** **99 = Other** **Specify:**_____

**[b3] Concentration UNITS (2nd Column):** **1 = ml/cc** **2 = L** **3 = gm** **4 =per actuation (spray/puff)** **-1 = N/A (topical cream)** **99 = Other Specify:**_____

| | | | | |
|---|---|---|---|---|
| **[c] FREQUENCY Code:** | **3 = q8 / tid (every 8 hours or 3 times/day)** | **6 = qod (every other day)** | **7 = qweek (every week)** | **13 = qmonth (every month)** |
| **1 = q4 (every 4 hours)** | **4 = q12 / bid (every 12 hours or twice/day)** | **10 = triweek (3 times/week)** | **11 = q2week (every 2 weeks)** | **9 = PRN (as needed)** |
| **2 = q6 (every 6 hours)** | **5 = q24 / qday (every day or once/day)** | **14 = biweek (2 times/week)** | **12 = q3week (ever 3 weeks)** | **8 = other: Specify Other:** _____ |

| | B1a. **Medication** (Brand Name and/or Generic) | B1b. **Drug Code:** | B1c. How is the drug **taken[a]**? (see **ADMINISTRATION** codes) | B1e. **Volume of the dose** (or number of drops/puffs /nebulizer treatment/suppository) and indicated the units[b1] (**see VOLUME UNITS** codes) | B1f. **Concentration** This is a measurement unit per a specific volume. (Refer to the medication label) Indicate the **measuring unit[b2]** in the 1st column and the **volume unit[b3]** in the 2nd column. (see **CONCENTRATION UNITS** codes) | | B5. What is the **frequency[c]** that drug suppose be taken? (see **FREQUENCY** codes) |
|---|---|---|---|---|---|---|---|
| *0* | **Amoxicillin suspension** | ***0 2 - 0 1 - 0 0*** | ___ ***1*** | ***5*** *Unit:* ___ ***1*** | ***2 5 0 . 0 0 0*** *Unit:* ___ ***2*** | ___ ___ ***5*** *Unit:* ___ ***1*** | ___ ***3*** |

# ALPHABETICAL LIST OF MEDICATIONS (revised 08-01-16)

| | |
|---|---|
| | **A** |
| 99-01-99 | **Acetaminophen (Tylenol)** |
| 01-09-99 | **Acetazolamide (Diamox)** |
| 13-03-00 | **Acidophilus** |
| 02-02-00 | **Acyclovir (Zovirax)** |
| 06-03-01 | **Albuterol (Ventolin, Preventil)** |
| 13-02-01 | **Alfacalcidol (One-alpha)** |
| 15-00-00 | **Allopurinol (Zyloprim)** |
| 01-09-02 | **Amiloride (Midamor)** |
| 01-10-00 | **Amiloride-Hydrochlorothiazide (Moduretic)** |
| 13-05-00 | **AMINO ACID SUPPLEMENT** |
| 01-06-00 | **Amlodipine (Norvasc)** |
| 02-01-00 | **Amoxicillin (Amoxil, Augmentin)** |
| 07-02-00 | **Amphetamine-Dextroamphetamine (Adderall)** |
| 03-99-00 | **Anemia Medication – Other** |
| 10-03-99 | **Antacid – Other** |
| 99-99-00 | **Antitussive - Dextromethorphan (Delsym)** |
| 07-03-00 | **Aripiprazole (Abilify)** |
| 13-01-02 | **Ascorbic Acid** |
| 99-01-99 | **Aspirin** |
| 01-03-00 | **Atenolol (Tenormin)** |
| 08-00-00 | **Atorvastatin (Lipitor)** |
| 99-99-00 | **Aurodex** |
| 04-02-00 | **Azathioprine (Imuran)** |
| 06-02-00 | **Azelastine (Astelin)** |
| 02-01-00 | **Azithromycin (Zithromax)** |
| | **B** |
| 01-01-00 | **Benazepril (Lotensin)** |
| 11-01-00 | **Bethanechol (Urecholine)** |
| 10-02-00 | **Bisacodyl (Ducolax)** |
| 01-03-00 | **Bisoprolol (Zebata)** |
| 06-01-00 | **Budesonide (Pulmicort)** |
| 07-01-00 | **Bupropion (Wellbutrin, Zyban)** |
| | **C** |
| 13-02-01 | **Calcitriol (Rocaltrol)** |
| 12-01-00 | **Calcium Carbonate (TUMS)** |
| 13-02-02 | **Calcium Carbonate with Vitamin D Supplement** |
| 12-01-00 | **Calcium salts (PhosLo)** |
| 13-02-02 | **Calcium Vitamin D Supplement** |
| 13-06-00 | **CALORIC NUTRITIONAL SUPPLEMENT** |
| 01-02-00 | **Candesartan (Atacand)** |
| 01-01-00 | **Captopril (Capoten)** |
| 09-00-00 | **Carbamazepine (Tegretol)** |
| 01-05-00 | **Carvedilol (Coreg)** |
| 02-01-00 | **Cefuroxime (Ceftin)** |
| 13-01-99 | **Centrium Etc.** |
| 02-01-00 | **Cephalexin (Keflex)** |
| 02-01-00 | **Cephalosporins** |
| 06-02-00 | **Cetirizine (Zyrtec)** |
| 13-01-99 | **Children's Multivitamin** |
| 13-03-00 | **Chlorophil** |
| 01-09-03 | **Chlorothiazide (Diuril)** |
| 06-02-00 | **Chlorpheniramine (Rynatan, Rondec-DM, R-Tannate)** |
| 10-03-01 | **Cimetidine (Tagamet)** |
| 07-01-00 | **Citalopram (Celexa)** |
| 10-05-02 | **CITRATE AND CITRIC ACID (Bicitra, Polycitra)** |
| 02-01-00 | **Clarithromycin (Biaxin)** |
| 02-01-00 | **Clindamycin (Cleocin)** |

# ALPHABETICAL LIST OF MEDICATIONS (revised 08-01-16)

| | |
|---|---|
| 01-07-00 | **Clonidine (Catapres)** |
| 02-03-00 | **Clotrimazole (Betamethasone, Lotrimin, Lotrisone, Mycelex)** |
| 13-07-00 | **Complete Omega** |
| 99-99-00 | **Contraceptive - Medroxyprogesterone (Depo-Provera)** |
| 13-01-99 | **Cranberry Tablet** |
| 04-02-00 | **Cyclophosphamide (Cytoxan)** |
| 04-02-00 | **Cyclosporine (Sandimmune, Neoral)** |
| 06-02-00 | **Cyproheptadine (Periactin)** |
| 13-04-02 | **CYSTEAMINE (CYSTAGON)** |
| | **D** |
| 03-01-02 | **Darbepoeitin alfa (Aranesp)** |
| 99-99-00 | **Depo-Provera** |
| 06-02-00 | **Desloratadine (Clarinex)** |
| 04-01-00 | **Desonide (DesOwen, Tridesilon)** |
| 07-02-00 | **Dexmethylphenidate (Focalin)** |
| 13-99-00 | **Dietary Supplement – Other** |
| 10-99-00 | **Digestive System Medication – Other** |
| 01-06-00 | **Diltiazem (Cardizem, Tiazac)** |
| 06-02-00 | **Diphenhydramine (Benadryl)** |
| 10-04-00 | **Diphenoxylate and Atropine (Lomotil)** |
| 13-02-02 | **Di-Vi-Sol** |
| 10-02-00 | **Docusate (Colace, Senna)** |
| 01-04-00 | **Doxazosin (Cardura)** |
| 13-02-02 | **Doxercalciferol (Hectorol)** |
| 13-02-02 | **Doxercaldreron Nectrol** |
| 02-01-00 | **Doxycycline (Vibramycin)** |
| 07-01-00 | **Duloxetine (Cymbalta)** |
| | **E** |
| 01-01-00 | **Enalapril (Vasotec)** |
| 06-03-99 | **Epinephrine (Adrenalin, Epipen)** |
| 13-02-02 | **Ergo Calciferol ( Drisdol)** |
| 03-01-01 | **Erythropoeitin (Epogen, Procrit)** |
| 03-01-99 | **ESA – Other** |
| 07-01-00 | **Escitalopram (Lexapro)** |
| 10-03-02 | **Esomeprazole (Nexium)** |
| | **F** |
| 10-03-01 | **Famotidine (Pepcid)** |
| 01-06-00 | **Felodipine (Plendil)** |
| 03-02-00 | **Ferrous Sulphate (Fer-in-sol)** |
| 06-02-00 | **Fexofenadine (Allegra, Allegra-D)** |
| 13-07-00 | **Fish Oil** |
| 13-03-00 | **Floranex Lactobacillus** |
| 04-01-00 | **Fludrocortisone (Florinef)** |
| 02-01-00 | **Fluoroquinolones (Ciprofloxacin, Cipro)** |
| 06-01-00 | **Fluticasone (Advair, Flovent)** |
| 13-01-02 | **Folic Acid (Niferex, Leucovorin)** |
| 01-01-00 | **Fosinopril (Monopril)** |
| 01-09-01 | **Furosemide (Lasix)** |
| | **G** |
| 13-01-02 | **Glyco-Bears Dietary Supplement** |
| 11-01-00 | **Glycopyrrolate (Robinol)** |
| 01-07-00 | **Guanfacine (Intuniv, Tenex)** |
| | **H** |
| 01-08-00 | **Hydralazine (Apresoline)** |
| 01-09-03 | **Hydrochlorothiazide** |

# ALPHABETICAL LIST OF MEDICATIONS (revised 08-01-16)

| | |
|---|---|
| 04-02-00 | **Hydroxychloroquine (Plaquenil)** |
| 11-01-00 | **Hyoscyamine (Levsin)** |
| | **I** |
| 99-01-01 | **Ibuprofen (Motrin, Advil, Midol)** |
| 07-01-00 | **Imipramine (Tofranil)** |
| 04-99-00 | **Immunosuppressive Meds – Other** |
| 14-01-00 | **Insulin Aspart (NovoLog)** |
| 14-01-00 | **Insulin Lispro (Humalog Insulin)** |
| 01-02-00 | **Irbesartan (Avapro)** |
| 03-02-00 | **IRON SUPPLEMENTATION** |
| 01-06-00 | **Isradipine (DynaCirc)** |
| | **J** |
| 13-04-01 | **Joules (Joules Solution)** |
| | **K** |
| 13-04-01 | **K-Phos-Neutral** |
| | **L** |
| 01-05-00 | **Labetolol (Normodyne)** |
| 09-00-00 | **Lamotrigine (Lamictal)** |
| 10-03-02 | **Lansoprazole (Prevacid)** |
| 13-01-02 | **L-Carnitine (Carnitor)** |
| 13-01-02 | **Leucovorin Calcium (Wellcovorin)** |
| 06-03-01 | **Levalbuterol (Xopenex)** |
| 09-00-00 | **Levetiracetam (Keppra)** |
| 14-02-00 | **Levothyroxine (Levoxyl, L-Thryoxine)** |
| 14-02-00 | **Levothyroxine Sodium (Synthroid)** |
| 01-01-00 | **Lisinopril (Prinivil, Zestril)** |
| 01-10-00 | **Lisnopril-Hydrochlorothiazide (Lisinop-Hcz, Prinizide, Zestoretic)** |
| 06-02-00 | **Loratadine (Claritin)** |
| 01-02-00 | **Losartan (Cozaar)** |
| 01-10-00 | **Losartan-Hydrochlorothiazide (Hyzaar)** |
| 08-00-00 | **Lovastatin (Advicor, Altoprev, Mevacor)** |
| | **M** |
| 13-04-01 | **Maginate (OTC magnesium supplement)** |
| 13-04-01 | **Magnesium (Maginex)** |
| 13-04-01 | **Magnesium Chloride** |
| 13-04-01 | **Magnesium Gluconate (Magonate)** |
| 13-04-01 | **Magnesium Oxide (Mag-Ox)** |
| 07-04-00 | **Melatonin** |
| 04-02-00 | **Mesalamine (Asacol, Pentasa)** |
| 14-01-00 | **Metformin (Fortamet)** |
| 04-02-00 | **Methotrexate (Amethopterin, Rheumatrex, Trexall)** |
| 07-02-00 | **Methylphenidate (Concerta, Metadate)** |
| 04-01-00 | **Methylprednisolone** |
| 10-01-00 | **Metoclopramide (Reglan)** |
| 01-09-99 | **Metolazone (Zaroxolyn)** |
| 01-03-00 | **Metoprolol (Lopressor, Toprol XL)** |
| 02-01-00 | **Metronidazole (Flagyl)** |
| 07-01-00 | **Mirtazapine (Remeron)** |
| 06-01-00 | **Mometasone Furoate (Nasonex)** |
| 06-99-00 | **Montelukast (Singulair)** |
| 07-99-00 | **Mood/Behavior Medication – Other** |
| 04-02-00 | **Mycophenolate mofetil (Cellcept)** |
| | **N** |
| 13-01-01 | **Nephro-Vite, Nephrocaps, Nephro, Replavite** |
| 01-06-00 | **Nifedipine (Adalat, Procardia)** |
| 03-02-00 | **Niferex** |

# ALPHABETICAL LIST OF MEDICATIONS (revised 08-01-16)

| | |
|---|---|
| 02-01-00 | **Nitrofurantoin (Furadantin, Macrobid, Macrodantin)** |
| 10-03-01 | **Nizatidine (Axid)** |
| 13-03-00 | **Noni Juice** |
| 99-99-00 | **Nutritional Supplement** |
| 02-03-00 | **Nystatin (Mycostatin, Pedi-Dri)** |
| | **O** |
| 07-03-00 | **Olanzapine (Zyprexa)** |
| 01-02-00 | **Olmesartan (Benicar)** |
| 13-07-00 | **Omega 3 Fatty Acid** |
| 10-03-02 | **Omeprazole (Priolsec)** |
| 10-01-00 | **Ondansetron (Zofran)** |
| 99-01-99 | **Opioids - Tylenol with Codeine** |
| 02-02-00 | **Oseltamivir (Tamiflu)** |
| 99-99-00 | **OTC Cough and Cold Products** |
| 99-99-00 | **Otic Analgesic - Antipyrine and Benzocaine (Aurodex)** |
| 09-00-00 | **Oxcarbazepine (Trileptal)** |
| 11-01-00 | **Oxybutynin (Ditropan, Ditropan XL, Oxytrol)** |
| | **P** |
| 10-03-02 | **Pantoprazole (Protonix)** |
| 02-01-00 | **Penicillin (Bicillin)** |
| 11-01-00 | **Phenazopyridine (Pyridium)** |
| 12-02-00 | **Phosphate/Potassium Binder Meds – Other** |
| 14-01-00 | **Pioglitazone Hydrochloride (Actos)** |
| 10-02-00 | **Polyethylene (Lactulose, Miralax, Glycolax)** |
| 13-04-01 | **Potassium Chloride (K-Dur, Klorconr)** |
| 13-04-01 | **Potassium Phosphate (Neutra-Phos)** |
| 08-00-00 | **Pravastatin (Proavachol, Pravigard)** |
| 01-04-00 | **Prazosin (Minipress)** |
| 04-01-00 | **Prednisone** |
| 10-01-00 | **Promethazine (Phenergan)** |
| 01-03-00 | **Propranolol (Inderal)** |
| | **Q** |
| 07-03-00 | **Quetiapine (Seroquel)** |
| 01-01-00 | **Quinapril (Accupril)** |
| | **R** |
| 01-01-00 | **Ramipril (Altace)** |
| 10-03-01 | **Ranitidine (Zantac)** |
| 07-03-00 | **Risperidone (Risperdal)** |
| 08-00-00 | **Rosuvastatin (Crestor)** |
| | **S** |
| 07-01-00 | **Sertaline (Zoloft)** |
| 12-01-00 | **Sevelamer (Renagel)** |
| 10-02-00 | **Simethicone (Maalox, Mylanta, Gas-X, Milk of Magnesia, Lactobacillus)** |
| 99-99-00 | **Similac 6040 (Formula)** |
| 08-00-00 | **Simvastatin (Zocor)** |
| 10-05-01 | **SODIUM BICARBONATE** |
| 13-04-01 | **Sodium Chloride** |
| 99-99-00 | **Sodium Chloride Inhalation** |
| 13-01-03 | **Sodium Fluoride (Ethedent Chewable, Fluoritab, Fluor-A-Day)** |
| 13-04-01 | **Sodium Phosphate (Na Phosphate)** |
| 12-02-00 | **Sodium Polystyrene Sulfonate (Kayexalate)** |
| 05-00-00 | **Somatren (Protropin)** |
| 05-00-00 | **Somatropin (Genotropin Humatrope, Nutropin)** |
| | **T** |
| 04-02-00 | **Tacrolimus, (FK506, Prograf)** |
| 01-04-00 | **Tamsulosin (Flomax)** |

# ALPHABETICAL LIST OF MEDICATIONS (revised 08-01-16)

| | |
|---|---|
| 01-02-00 | **Telmisartan (Micardis)** |
| 14-02-00 | **Thynoxine (Thyroid Supplement)** |
| 02-01-00 | **Tobramycin (Nebcin)** |
| 11-01-00 | **Tolterodine (Detrol, Detrol LA)** |
| 06-01-00 | **Triamcinolone (Allernaze, Nasacort, Tri-nasal)** |
| 11-01-00 | **Trihexyphenidyl (Artane)** |
| 02-01-00 | **Trimethoprim-Sulfamethoxazole (Bactrim, Sulfatrim, Septra)** |
| | **U** |
| 99-99-99 | **UNKNOWN MEDICATION** |
| | **V** |
| 09-00-00 | **Valproic Acid (Depakene, Depakote, Divalproex sodium)** |
| 01-02-00 | **Valsartan (Diovan)** |
| 11-01-00 | **Vasopress in analog Desmopressin (DDAVP)** |
| 07-01-00 | **Venlafaxine (Effexor)** |
| 01-06-00 | **Verapamil (Isoptin, Calan, Nu-Verap, Novo-Veramil)** |
| 13-01-99 | **Vitamin B** |
| 13-01-99 | **Vitamin C** |
| 13-02-02 | **Vitamin D 25, D3** |
| 13-01-02 | **Vitamin E** |
| | **X** |
| 99-99-00 | **Xanthine Oxidase Inhibitor - Allopurinol (Zyloprim)** |
| | **Z** |
| 13-02-01 | **Zemplar (Paricalcitol)** |
| 13-01-02 | **Zinc** |

# MEDICATIONS LIST BY DRUG CLASSIFICATION (revised 08/01/16)

| | ANTIHYPERTENSIVE MEDICATION |
|---|---|
| **01-00-00** | **ACE INHIBITORS** |
| 01-01-00 | Benazepril (Lotensin) |
| 01-01-00 | Captopril (Capoten) |
| 01-01-00 | Enalapril (Vasotec) |
| 01-01-00 | Fosinopril (Monopril) |
| 01-01-00 | Lisinopril (Prinivil, Zestril) |
| 01-01-00 | Quinapril (Accupril) |
| 01-01-00 | Ramipril (Altace) |
| **01-02-00** | **ANGIOTENSIN RECEPTOR BLOCKERS (ARBs)** |
| 01-02-00 | Candesartan (Atacand) |
| 01-02-00 | Irbesartan (Avapro) |
| 01-02-00 | Losartan (Cozaar) |
| 01-02-00 | Olmesartan (Benicar) |
| 01-02-00 | Telmisartan (Micardis) |
| 01-02-00 | Valsartan (Diovan) |
| **01-03-00** | **BETA BLOCKERS** |
| 01-03-00 | Atenolol (Tenormin) |
| 01-03-00 | Bisoprolol (Zebata) |
| 01-03-00 | Metoprolol (Lopressor, Toprol XL) |
| 01-03-00 | Propranolol (Inderal) |
| **01-04-00** | **ALPHA BLOCKERS** |
| 01-04-00 | Doxazosin (Cardura) |
| 01-04-00 | Prazosin (Minipress) |
| 01-04-00 | Tamsulosin (Flomax) |
| **01-05-00** | **ALPHA/BETA BLOCKERS** |
| 01-05-00 | Carvedilol (Coreg) |
| 01-05-00 | Labetolol (Normodyne) |
| **01-06-00** | **CALCIUM CHANNEL BLOCKER** |
| 01-06-00 | Amlodipine (Norvasc) |
| 01-06-00 | Diltiazem (Cardizem, Tiazac) |
| 01-06-00 | Felodipine (Plendil) |
| 01-06-00 | Isradipine (DynaCirc) |
| 01-06-00 | Nifedipine (Adalat, Procardia) |
| 01-06-00 | Verapamil (Isoptin, Calan, Nu-Verap, Novo-Veramil) |
| **01-07-00** | **CENTRALLY ACTING ALPHA-2 AGONIST** |
| 01-07-00 | Clonidine (Catapres) |
| 01-07-00 | Guanfacine (Intuniv, Tenex) |
| **01-08-00** | **DIRECT VASODILATORS** |
| 01-08-00 | Hydralazine (Apresoline) |
| **01-09-01** | **DIURECTIC – LOOP** |
| 01-09-01 | Furosemide (Lasix) |
| **01-09-02** | **DIURETIC – POTASSIUM-SPARING** |
| 01-09-02 | Amiloride (Midamor) |
| **01-09-03** | **DIURECTIC – THIAZIDE** |
| 01-09-03 | Chlorothiazide (Diuril) |
| 01-09-03 | Hydrochlorothiazide |
| **01-09-99** | **DIURECTIC - OTHER** |
| 01-09-99 | Acetazolamide (Diamox) |
| 01-09-99 | Metolazone (Zaroxolyn) |
| **01-10-00** | **COMBINATION ANTIHYPERTENSIVE MEDS** |
| 01-10-00 | Amiloride/Hydrochlorothiazide (Moduretic) |
| 01-10-00 | Lisnopril/Hydrochlorothiazide (Lisinop/Hcz, Prinizide, Zestoretic) |
| 01-10-00 | Losartan/Hydrochlorothiazide (Hyzaar) |

| | ANTI-INFECTIOUS AGENTS |
|---|---|
| **02-01-00** | **ANTIBIOTICS - UTI PROPHYLAXIS** |
| 02-01-00 | Amoxicillin (Amoxil, Augmentin) |
| 02-01-00 | Azithromycin (Zithromax) |
| 02-01-00 | Cefuroxime (Ceftin) |
| 02-01-00 | Cephalexin (Keflex) |
| 02-01-00 | Cephalosporins |
| 02-01-00 | Clarithromycin (Biaxin) |
| 02-01-00 | Clindamycin (Cleocin) |
| 02-01-00 | Doxycycline (Vibramycin) |
| 02-01-00 | Fluoroquinolones (Ciprofloxacin, Cipro) |
| 02-01-00 | Metronidazole (Flagyl) |
| 02-01-00 | Nitrofurantoin (Furadantin, Macrobid, Macrodantin) |
| 02-01-00 | Penicillin (Bicillin) |
| 02-01-00 | Tobramycin (Nebcin) |
| 02-01-00 | Trimethoprim-Sulfamethoxazole (Bactrim, Sulfatrim, Septra) |
| **02-02-00** | **ANTIVIRAL** |
| 02-02-00 | Acyclovir (Zovirax) |
| 02-02-00 | Oseltamivir (Tamiflu) |
| **02-03-00** | **ANTIFUNGAL** |
| 02-03-00 | Clotrimazole (Betamethasone, Lotrimin, Lotrisone, Mycelex) |
| 02-03-00 | Nystatin (Mycostatin, Pedi-Dri) |

# MEDICATIONS LIST BY DRUG CLASSIFICATION (revised 08/01/16)

| | ANEMIA MEDICATION |
|---|---|
| **03-01-01** | **ESA – ERYTHOPOIETIN** |
| 03-01-01 | Erythropoeitin (Epogen, Procrit) |
| **03-01-02** | **ESA – DARBEPOETIN ALFA** |
| 03-01-02 | Darbepoeitin alfa (Aranesp) |
| **03-01-99** | **ESA – OTHER** |
| | |
| **03-02-00** | **IRON SUPPLEMENTATION** |
| 03-02-00 | Ferrous Sulphate (Fer-in-sol) |
| 03-02-00 | Niferex |
| **03-99-00** | **OTHER ANEMIA MEDICATION** |

| | IMMUNOSUPPRESSIVES |
|---|---|
| **04-01-00** | **CORTICOSTEROIDS** |
| 04-01-00 | Desonide (DesOwen, Tridesilon) |
| 04-01-00 | Fludrocortisone (Florinef) |
| 04-01-00 | Methylprednisolone |
| 04-01-00 | Prednisone |
| **04-02-00** | **ANTINEOPLASTIC / CHEMOTHERAPEUTIC AGENTS** |
| 04-02-00 | Azathioprine (Imuran) |
| 04-02-00 | Cyclophosphamide (Cytoxan) |
| 04-02-00 | Cyclosporine (Sandimmune, Neoral) |
| 04-02-00 | Hydroxychloroquine (Plaquenil) |
| 04-02-00 | Mesalamine (Asacol, Pentasa) |
| 04-02-00 | Methotrexate (Amethopterin, Rheumatrex, Trexall) |
| 04-02-00 | Mycophenolate mofetil (Cellcept) |
| 04-02-00 | Tacrolimus, (FK506, Prograf) |
| **04-99-00** | **OTHER IMMUNOSUPPRESSIVE MED** |

| | GROWTH HORMONES |
|---|---|
| 05-00-00 | Somatren (Protropin) |
| 05-00-00 | Somatropin (Genotropin Humatrope, Nutropin) |

| | ASTHMA/ALLERGY MEDICATIONS |
|---|---|
| **06-01-00** | **INHALED CORTICOSTEROIDS** |
| 06-01-00 | Budesonide (Pulmicort) |
| 06-01-00 | Fluticasone (Advair, Flovent) |
| 06-01-00 | Mometasone Furoate (Nasonex) |
| 06-01-00 | Triamcinolone (Allernaze, Nasacort, Tri-nasal) |
| **06-02-00** | **ANTIHISTAMINES (OTC & PRESCRIPTION MEDS)** |
| 06-02-00 | Azelastine (Astelin) |
| 06-02-00 | Cetirizine (Zyrtec) |
| 06-02-00 | Chlorpheniramine (Rynatan, Rondec-DM, R-Tannate) |
| 06-02-00 | Cyproheptadine (Periactin) |
| 06-02-00 | Desloratadine (Clarinex) |
| 06-02-00 | Diphenhydramine (Benadryl) |
| 06-02-00 | Fexofenadine (Allegra, Allegra-D) |
| 06-02-00 | Loratadine (Claritin) |
| **06-03-01** | **SHORT ACTING B2 AGONIST** |
| 06-03-01 | Albuterol (Ventolin, Preventil) |
| 06-03-01 | Levalbuterol (Xopenex) |
| **06-03-99** | **OTHER BRONCHODILATOR** |
| 06-03-99 | Epinephrine (Adrenalin, Epipen) |
| **06-99-00** | **OTHER ASTHMA/ALLERGY MEDICATION** |
| 06-99-00 | Montelukast (Singulair) |

| | MOOD/BEHAVIOR MEDICATIONS |
|---|---|
| **07-01-00** | **ANTIDEPRESSANT** |
| 07-01-00 | Bupropion (Wellbutrin, Zyban) |
| 07-01-00 | Citalopram (Celexa) |
| 07-01-00 | Duloxetine (Cymbalta) |
| 07-01-00 | Escitalopram (Lexapro) |
| 07-01-00 | Imipramine (Tofranil) |
| 07-01-00 | Mirtazapine (Remeron) |
| 07-01-00 | Sertaline (Zoloft) |
| 07-01-00 | Venlafaxine (Effexor) |
| **07-02-00** | **CNS STIMULANTS (ADD and ADHD MEDICATIONS)** |
| 07-02-00 | Amphetamine/Dextroamphetamine (Adderall) |
| 07-02-00 | Dexmethylphenidate (Focalin) |
| 07-02-00 | Methylphenidate (Concerta, Metadate) |

# MEDICATIONS LIST BY DRUG CLASSIFICATION (revised 08/01/16)

| | |
|---|---|
| **07-03-00** | **ANTIPSYCHOTICS** |
| 07-03-00 | Aripiprazole (Abilify) |
| 07-03-00 | Olanzapine (Zyprexa) |
| 07-03-00 | Quetiapine (Seroquel) |
| 07-03-00 | Risperidone (Risperdal) |
| **07-04-00** | **SLEEP MEDICATION** |
| 07-04-00 | Melatonin |
| **07-99-00** | **OTHER MOOD/BEHAVIOR MEDICATIONS** |

| | |
|---|---|
| | **LIPID LOWERING MEDICATIONS** |
| 08-00-00 | Atorvastatin (Lipitor) |
| 08-00-00 | Lovastatin (Advicor, Altoprev, Mevacor) |
| 08-00-00 | Pravastatin (Proavachol, Pravigard) |
| 08-00-00 | Rosuvastatin (Crestor) |
| 08-00-00 | Simvastatin (Zocor) |

| | |
|---|---|
| | **SEIZURE/ANTIEPILEPTIC MEDICATIONS** |
| 09-00-00 | Carbamazepine (Tegretol) |
| 09-00-00 | Lamotrigine (Lamictal) |
| 09-00-00 | Levetiracetam (Keppra) |
| 09-00-00 | Oxcarbazepine (Trileptal) |
| 09-00-00 | Valproic Acid (Depakene, Depakote, Divalproex sodium) |

| | |
|---|---|
| | **DIGESTIVE SYSTEM MEDICATIONS** |
| **10-01-00** | **ANTIEMETICS & GI MOTILITY AGENTS** |
| 10-01-00 | Metoclopramide (Reglan) |
| 10-01-00 | Ondansetron (Zofran) |
| 10-01-00 | Promethazine (Phenergan) |
| **10-02-00** | **LAXATIVES & STOOL SOFTNERS** |
| 10-02-00 | Bisacodyl (Ducolax) |
| 10-02-00 | Docusate (Colace, Senna) |
| 10-02-00 | Polyethylene (Lactulose, Miralax, Glycolax) |
| 10-02-00 | Simethicone (Maalox, Mylanta, Gas-X, Milk of Magnesia, Lactobacillus) |
| **10-03-01** | **ANTACIDS – H2-RECEPTOR BLOCKERS** |
| 10-03-01 | Cimetidine (Tagamet) |
| 10-03-01 | Famotidine (Pepcid) |
| 10-03-01 | Nizatidine (Axid) |
| 10-03-01 | Ranitidine (Zantac) |
| **10-03-02** | **ANTACIDS – PROTON-PUMPINHIBITORS** |
| 10-03-02 | Esomeprazole (Nexium) |
| 10-03-02 | Lansoprazole (Prevacid) |
| 10-03-02 | Omeprazole (Priolsec) |
| 10-03-02 | Pantoprazole (Protonix) |
| **10-03-99** | **OTHER ANTACIDS** |

| | |
|---|---|
| **10-04-00** | **ANTIDIARRHEALS** |
| 10-04-00 | Diphenoxylate and Atropine (Lomotil) |
| **10-05-01** | **SODIUM BICARBONATE** |
| **10-05-02** | **CITRATE AND CITRIC ACID (Bicitra, Polycitra)** |
| **10-99-00** | **OTHER DIGESTIVE SYSTEM MEDICATIONS** |

| | |
|---|---|
| | **BLADDER/URINARY SYSTEM MEDICATIONS** |
| **11-01-00** | **ANTICHOLINGERGICS** |
| 11-01-00 | Bethanechol (Urecholine) |
| 11-01-00 | Glycopyrrolate (Robinol) |
| 11-01-00 | Hyoscyamine (Levsin) |
| 11-01-00 | Oxybutynin (Ditropan, Ditropan XL, Oxytrol) |
| 11-01-00 | Phenazopyridine (Pyridium) |
| 11-01-00 | Tolterodine (Detrol, Detrol LA) |
| 11-01-00 | Trihexyphenidyl (Artane) |
| 11-01-00 | Vasopress in analog Desmopressin (DDAVP) |

| | |
|---|---|
| | **PHOSPHATE AND POTASSIUM BINDERS** |
| **12-01-00** | **PHOSPHATE BINDER** |
| 12-01-00 | Calcium Carbonate (TUMS) |
| 12-01-00 | Calcium salts (PhosLo) |
| 12-01-00 | Sevelamer (Renagel) |
| **12-02-00** | **POTASSIUM BINDER** |
| 12-02-00 | Sodium Polystyrene Sulfonate (Kayexalate) |
| **12-99-00** | **OTHER PHOSPHATE/POTASSIUM BINDER MED** |

# MEDICATIONS LIST BY DRUG CLASSIFICATION (revised 08/01/16)

| | DIETARY SUPPLEMENT |
|---|---|
| **13-01-01** | **MULTIVITAMINS FOR KIDNEY DISEASE** |
| 13-01-01 | Nephro-Vite, Nephrocaps, Nephro, Replavite |
| **13-01-02** | **VITAMIN/MINERAL SUPPLEMENT** |
| 13-01-02 | Ascorbic Acid |
| 13-01-02 | Folic Acid (Niferex, Leucovorin) |
| 13-01-02 | Glyco-Bears Dietary Supplement |
| 13-01-02 | L-Carnitine (Carnitor) |
| 13-01-02 | Leucovorin Calcium (Wellcovorin) |
| 13-01-02 | Vitamin E |
| 13-01-02 | Zinc |
| **13-01-03** | **FLUORIDE** |
| 13-01-03 | Sodium Fluoride (Ethedent Chewable, Fluoritab, Fluor-A-Day) |
| **13-01-99** | **OTHER MULTIVITAMINS** |
| 13-01-99 | Centrium Etc. |
| 13-01-99 | Children's Multivitamin |
| 13-01-99 | Cranberry Tablet |
| 13-01-99 | Vitamin B |
| 13-01-99 | Vitamin C |
| **13-02-01** | **ACTIVE VITAMIN D** |
| 13-02-01 | Alfacalcidol (One-alpha) |
| 13-02-01 | Calcitriol (Rocaltrol) |
| 13-02-01 | Zemplar (Paricalcitol) |
| **13-02-02** | **INACTIVE VITAMIN D** |
| 13-02-02 | Calcium Vitamin D Supplement |
| 13-02-02 | Calcium Carbonate with Vitamin D Supplement |
| 13-02-02 | Di-Vi-Sol |
| 13-02-02 | Doxercalciferol (Hectorol) |
| 13-02-02 | Doxercaldreron Nectrol |
| 13-02-02 | Ergo Calciferol ( Drisdol) |
| 13-02-02 | Vitamin D 25, D3 |
| **13-03-00** | **HERBAL SUPPLEMENT** |
| 13-03-00 | Acidophilus |
| 13-03-00 | Chlorophil |
| 13-03-00 | Floranex Lactobacillus |
| 13-03-00 | Noni Juice |
| **13-04-01** | **ELECTROLYTE REPLACEMENT** |
| 13-04-01 | Joules (Joules Solution) |
| 13-04-01 | K-Phos-Neutral |
| 13-04-01 | Maginate (OTC magnesium supplement) |
| 13-04-01 | Magnesium (Maginex) |
| 13-04-01 | Magnesium Chloride |
| 13-04-01 | Magnesium Gluconate (Magonate) |
| 13-04-01 | Magnesium Oxide (Mag-Ox) |
| 13-04-01 | Potassium Chloride (K-Dur, Klorconr) |
| 13-04-01 | Potassium Phosphate (Neutra-Phos) |
| 13-04-01 | Sodium Chloride |
| 13-04-01 | Sodium Phosphate (Na Phosphate) |
| **13-04-02** | **CYSTEAMINE (CYSTAGON)** |
| **13-05-00** | **AMINO ACID SUPPLEMENT** |
| **13-06-00** | **CALORIC NUTRITIONAL SUPPLEMENT** |
| **13-07-00** | **FISH OILS** |
| 13-07-00 | Complete Omega |
| 13-07-00 | Fish Oil |
| 13-07-00 | Omega 3 Fatty Acid |
| **13-99-00** | **OTHER DIETARY SUPPLEMENTS** |

# MEDICATIONS LIST BY DRUG CLASSIFICATION (revised 08/01/16)

| | ENDOCRINE SYSTEM MEDICATION |
|---|---|
| **14-01-00** | **INSULIN AND ORAL HYPOGLYCEMICS** |
| 14-01-00 | Insulin Aspart (NovoLog) |
| 14-01-00 | Insulin Lispro (Humalog Insulin) |
| 14-01-00 | Metformin (Fortamet) |
| 14-01-00 | Pioglitazone Hydrochloride (Actos) |
| **14-02-00** | **THYROID REPLACEMENT** |
| 14-02-00 | Levothyroxine (Levoxyl, L-Thryoxine) |
| 14-02-00 | Levothyroxine Sodium (Synthroid) |
| 14-02-00 | Thynoxine (Thyroid Supplement) |

| | XANTHINE OXIDASE INHIBITOR |
|---|---|
| 15-00-00 | Allopurinol (Zyloprim) |

| | OTHER MEDICATIONS |
|---|---|
| **99-01-01** | **ANALGESICS, IBUPROPHEN (NSAID)** |
| 99-01-01 | Ibuprofen (Motrin, Advil, Midol) |
| **99-01-99** | **ANALGESICS, ASPIRIN/ACETAMINOPHEN** |
| 99-01-99 | Acetaminophen (Tylenol) |
| 99-01-99 | Aspirin |
| 99-01-99 | Opioids - Tylenol with Codeine |
| **99-99-00** | **OTHER MEDICATION SUPPLEMENT** |
| 99-99-00 | Antitussive - Dextromethorphan (Delsym) |
| 99-99-00 | Aurodex |
| 99-99-00 | Contraceptive - Medroxyprogesterone (Depo-Provera) |
| 99-99-00 | Depo-Provera |
| 99-99-00 | Nutritional Supplement |
| 99-99-00 | OTC Cough and Cold Products |
| 99-99-00 | Otic Analgesic - Antipyrine and Benzocaine (Aurodex) |
| 99-99-00 | Similac 6040 (Formula) |
| 99-99-00 | Sodium Chloride Inhalation |
| 99-99-00 | Xanthine Oxidase Inhibitor - Allopurinol (Zyloprim) |

| | |
|---|---|
| **99-99-99** | **UNKNOWN MEDICATION** |

# SPECIMEN COLLECTION FORM for Visit 1a (L01)

## CKiD Chronic Kidney Disease in Children Cohort Study (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: 0 1 a

A3. FORM VERSION: 0 3 / 0 1 / 1 8

A4. DATE OF VISIT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. FORM COMPLETED BY (INITIALS): ___ ___ ___

**The following samples should be collected.**

| **Samples:** | **Shipped to:** | **Shipped:** |
|---|---|---|
| **Serum** | **CBL** | **IMMEDIATELY** |
| **Serum** | **CBL** | **Batched (Ship in Jan, Apr, Jul or Oct)** |
| **Urine** | **CBL** | **IMMEDIATELY** |
| **Iohexol Blood*** | **CBL** | **IMMEDIATELY** |

*** COLLECT IOHEXOL BLOOD DRAW: Only if Cohort 3 participants who consent to iohexol protocol or Cohorts 1 & 2 participants had previous iGFR>90**

**BATCHED SAMPLES SHOULD BE SHIPPED QUARTERLY (Jan, Apr, July or Oct) OR MORE OFTEN IF DESIRED BY THE SITE COORDINATOR!**

**Samples should NOT be stored for more than one year.**
**For specific questions, contact your CCC prior to shipment.**

## SECTION B: PREGNANCY TEST AND FIRST MORNING URINE COLLECTION

B1. Is participant a female of child-bearing potential?

Yes..... 1 **(See PROMPT Below)**

No..... 2 **(Skip to B3)**

***PROMPT: QUESTION B2 IS FOR FEMALE PARTICIPANTS OF CHILD-BEARING POTENTIAL ONLY. URINE PREGNANCY TEST DATE MUST FALL WITHIN 72 HOURS BEFORE STUDY VISIT DATE.***

***If performing iohexol protocol, B2 MUST BE COMPLETED BEFORE IOHEXOL TESTING IS INITIATED.***

B2. a. Urine pregnancy test date: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

b. Urine pregnancy results:

Positive..... 1 **(END; COMPLETE TRANSITIONAL (TRS01) FORM)**

Negative..... 2

# FIRST MORNING URINE COLLECTION

Obtain urine collected at home in the specimen container that was shipped to the family before the visit.
If URINE WAS NOT COLLECTED at home, collect FRESH urine sample during CKiD visit.

↓

Pour at least 1 mL of urine into the CBL transport tube.

↓

Check that all information is correct on the urine collection tube and follow packaging instructions and ship to CBL.

**Reasons Code List*:** 1= Not required; 2 = Difficult Urine Collection; 3 = Participant Refused; 4 = Collection Contamination; 5 = Inadvertently Destroyed; 6 = Oversight; 7=Insufficient Volume

| Sample Type (Required Volume): | (a) Sample Obtained: Yes | (a) Sample Obtained: No | (b) If No, specify reason *SEE CODE LIST ABOVE | (c) Additional Requirements: |
|---|---|---|---|---|
| B3. Urine Creatinine, Urine Protein, Urine Albumin (1 mL–10 mL) | 1 **(skip to c→)** | 2 | __ __ **(skip to C1)** | i. Is this a first morning urine sample? Yes.....1 No.....2<br>ii. Time of Collection: __ __ : __ __ 1 = am, 2 = pm |

## SECTION C: Visit 1a BLOOD DRAW (Select the Type of Consent Obtained, option 1 or 2)

**1 If participant is completing study visit, without iohexol protocol:** Collect **4.5-5.5** mL from all participants (regardless of weight)

If **< 30 kg**, immediately transfer **(using 18 gauge needle)** or draw:

- 2 mL into Tiger-Top SSTs for CBL
- 1 mL in lavender-top tube for local CBC *(tube not provided in CBL kit)*
- 1.5 mL in appropriate tube *(not provided)* for local Renal Panel
- ***1 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)***

**2 For Participant Completing Iohexol Study Visit:**

For IOHEXOL study visits, collect:

- ***1mL of additional blood into Tiger Top SST for CBL Iohexol Blank (B0) blood sample***

Iohexol is infused at the time of initial blood draw. Refer to page 6 for **Instructions for Iohexol Infusion and GFR Blood Draws.**

# SPECIMEN COLLECTION FORM for Visit 1a (L01)

## SECTION C: Visit 1a BLOOD DRAW PROCESSING

Initial blood draw with **Syringe(s)**

OR

Initial blood draw with **Vacutainer Method**: draw 1 mL directly into lavender-top tube for local CBC; draw 1.5 mL directly for local renal panel; draw 2 mL (3 mL if performing the iohexol protocol) directly into tiger-top SST

OR

Initial blood draw with **Butterfly**: draw 1 mL directly into lavender-top tube for local CBC; draw 1.5 mL directly for local renal panel; draw 2 mL (3 mL if performing iohexol protocol) directly into tiger-top SST

Immediately transfer 1 mL of whole blood into lavender-top tube for local CBC and 1.5 mL for local renal panel. Process and send to local lab for analysis and complete CBC and Local Renal Panel results forms (L04 & L03).

**Using 18 gauge needle**, immediately transfer remaining whole blood into tiger-top SST.

Invert the SST 5 times gently to mix.

Stand SST upright to allow clotting at room temperature for 30 mins and not more than 1 hour (60 mins).

Centrifuge SST at MAX SPEED between 1100-1300 g (3000rpm with 10cm radius rotor) for 10 minutes in swinghead units **OR** 15 minutes in fixed angle units (balance tube in centrifuge). *If incomplete separation, centrifuge again for 10-15 minutes.

**If sample is GROSSLY HEMOLYZED.**

You must send hemolyzed sample to CBL. Also, if the sample is **GROSSLY HEMOLYZED (Dark Red),** collect 1 mL of additional blood in a SST. Centrifuge and then transfer serum into the extra Orange Top Transport Tube provided.

Follow packaging instructions and ship to CBL with accompanying forms. **No FRIDAY shipments.** Refrigerate specimen and ship on next business day.

**If sample is moderately, slightly or NOT HEMOLYZED, proceed with CBL preparation.**

**For IOHEXOL STUDY VISITS ONLY:**
**B0 sample**

Using the disposable pipette, pipette 0.5 mL of serum into Round-bottom Orange Top Transport Tube labeled "B0" for Iohexol Blank (B0) sample. Follow packaging instructions and ship to CBL with accompanying forms, iohexol blood draws and urine. **No FRIDAY shipments.** Refrigerate specimen and ship on next business day.

**CBL Studies**

Using the disposable pipette, pipette 0.5 mL of serum into Orange Top Transport Tube labeled "Serum CBL" for CBL renal/uric acid. Follow packaging instructions and ship to CBL with accompanying forms, iohexol blood draws and urine. **No FRIDAY shipments.** Refrigerate specimen and ship on next business day.

**Cystatin C**

Using the disposable pipette, pipette 0.5 mL of serum into Blue Screw-Top Cryovial for Cystatin C.
Store sample in freezer at -70°C or lower, batch up to 20 samples and ship on dry ice every four months to the CBL. When shipper is needed, complete "CBL Dry Ice Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/
Then, follow packaging instructions and ship to CBL with accompanying forms. **No FRIDAY shipments.** Ship on next business day.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ to notify appropriate personnel that sample(s) have been shipped to CBL.

# SPECIMEN COLLECTION FORM for Visit 1a (L01)

C1. ACTUAL TIME OF BLOOD DRAW ____ ____ : ____ ____ 1 = AM 2 = PM

***PROMPT: IF SUSPECTED BLOOD DRAW ADVERSE EVENT (i.e., infection), complete Adverse Event (ADVR) Form***

| **Reasons Code List*:** | 1= Not required | 4 = Red Blood Cell Contamination | 7 = Exceeds maximum allowable volume |
|---|---|---|---|
| | 2 = Difficult Blood Draw | 5 = Inadvertently Destroyed | |
| | 3 = Participant Refused | 6 = Oversight | |

| **Sample Type (Required Volume in Top Color Tube Type):** | **(a) Sample Obtained:** Yes / No | **(b) If No, specify reason** ***SEE CODE LIST ABOVE** | **(c) Additional Requirements:** |
|---|---|---|---|
| C2. Renal/ Uric Acid Chemistries (2.0 mL in Tiger Top SST) | 1 **(skip to c→)** / 2 | ___ **(skip to C3)** | Indicate the appearance of the serum after centrifuging.<br>Grossly (Dark Red).....1<br>Moderately (Red/Light Red).....2<br>Slightly (Pink)..... .....3<br>Not Hemolyzed (Yellow).....4 |
| C3. Cystatin C (1.0 mL in Tiger Top SST) | 1 **(skip to c→)** / 2 | ___ ___ **(skip to C4)** | Date Frozen:<br>___ ___ / ___ ___ /___ ___ ___ ___<br>M M D D Y Y Y Y |
| C4. Local CBC (1.0 mL in Lavender Top tube) | 1 **(skip to C5)** / 2 | ___ ___ **(skip to C5)** | **N/A** |
| C5. Local Renal Panel (1.5 mL in Local SST) | 1 **(skip to D2)** / 2 | ___ ___ **(skip to D2)** | **N/A** |

Sites can obtain results for lab values that have been identified as “KEY VARIABLES”. To obtain results, go the CKiD Nephron Website: **https://statepiaps8.jhsph.edu/nephron/groups/aspproc/**, click on “Report Menu” and choose the appropriate lab report (i.e., Selected Renal Panel Lab Variables Report.)

## SECTION D: OPTIONAL TESTS

## LOCAL LAB TEST (IF CLINICALLY INDICATED)

Check with the PI at your clinical site to determine whether or not it is **CLINICALLY INDICATED** to obtain urine for local lab. These are instances when the PI needs results immediately and/or the participant needs additional local labs performed (i.e., local Urine Creatinine and Urine Protein).

**QUESTION D1 HAS BEEN DELETED.**

D2. Was a urine protein to creatinine ratio assay performed at the clinical site's local laboratory?

Yes..... 1 → **Complete Local Urine Assay Results Form L06 ONLY if local labs are CLINICALLY INDICATED**

No..... 2

## IOHEXOL PROTOCOL

D3. Is the participant completing iohexol study visit? Yes, consent obtained..... 1

No..... 2 → **(End Form)**

## ONLY COMPLETE SECTIONS E & F IF PARTICIPANT IS COMPLETING IOHEXOL STUDY VISIT.

**Only Cohort 3 participants who consent to iohexol protocol or Cohorts 1 & 2 participants with previous iGFR>90 should complete iohexol protocol. If you have additional questions, contact CCC.**
**For an iohexol study visit, additional blood (including blood for the Iohexol "B0" Blank sample) should be collected for Iohexol-Based GFR.**

## SECTION E: INFUSION SYRINGE WEIGHT

E1. **SCALE MUST BE FIRST ZEROED BEFORE WEIGHING. REMOVE ALUMINUM FOIL PRIOR TO WEIGHING THE SYRINGE. THE SAME SCALE MUST BE USED TO WEIGH THE SYRINGE PRE AND POST IOXEHOL INFUSION.**

a. Syringe Weight **Pre- Iohexol Infusion**: ___ ___ . ___ ___ (g)

b. Syringe Weight **Post- Iohexol Infusion**: ___ ___ . ___ ___ (g) (Post-Infusion Weight should be **at least 6.0g** less than Pre-Infusion Weight. If Post-Infusion Weight is not at least 6g less, please confirm.)

## PRE AND POST SYRINGE WEIGHT MUST BE OBTAINED IN ORDER TO CALCULATE PARTICIPANT'S GFR.

## SECTION F: IOHEXOL – Refer to Instructions for Iohexol Infusion and GFR Blood Draws Flow Chart on Page 6

- **BEFORE** INFUSING **5 mL** of IOHEXOL, **SET TIMER = 0**. SIMULTANEOUSLY START TIMER AND BEGIN IOHEXOL INFUSION
- **COMPLETE INFUSION BETWEEN 1 TO 2 MINS.**
- LEAVE TIMER RUNNING THROUGHOUT IOHEXOL INFUSION AND SUBSEQUENT BLOOD DRAWS

# SPECIMEN COLLECTION FORM for Visit 1a (L01)

## Instructions for Iohexol Infusion and GFR Blood Draws

Place two IV lines (18-22 gauge polyethylene catheters) using two separate vascular access sites

---OR---

Place one butterfly and one IV line (18-22 gauge polyethylene catheter) using two separate vascular access sites; use tape to stabilize butterfly for iohexol infusion

--OR---

Use butterfly for pre-iohexol and individual blood draw sticks; use tape to stabilize butterfly for Iohexol infusion

↓

Complete pre-iohexol infusion blood draw according to instructions

↓

Start timer and infuse iohexol over 1-2 minutes

**If infusion site for iohexol IV or butterfly infiltrates, study MUST BE DISCONTINUED**

**Must wait at least 48 hours to repeat study, and repeat visit should occur within 3 months of initial**

↓

Flush with 10 mL normal saline to ensure infusion of all of the iohexol; **IOHEXOL IV OR BUTTERFLY MAY NOW BE REMOVED**

↓

**10 minutes post-infusion**
**CHECK POST-INFUSION VITALS**
**DO NOT DRAW BLOOD AT 10 MINUTES**

→ If rash develops, consider it a reaction to iohexol and **notify PI immediately**. Consider administering 1mg/kg Benadryl IV (maximum dose 50mg).

→ If systolic BP decreases > 25 mm Hg, diastolic BP decreases > 20 mm Hg or pulse increases > 20 beats per min, consider this an anaphylactic reaction to iohexol and **notify PI immediately**; consider administering 1 mg/kg Benadryl IV (maximum dose 50 mg) and draw up to 0.1 mL 1:1000 Epinephrine for SQ injection and 2 mg/kg Solumedrol IV if necessary.

↓

COMPLETE ADVERSE EVENT FORM and send to CCC for data entry

↓

Obtain post-infusion weight of syringe on the same scale as prior to infusion. Record weight on the Specimen Collection Form prior to shipment to the CCC

↓

Draw 1 ml of blood into SST at 120 mins (B1), and 300 mins (B2).

*For IV ONLY: Discard initial 1 mL blood waste at each blood draw (or per device guidelines)

*For IV ONLY: Flush after each blood draw with at least 3 mL normal saline

*Record the time each blood draw is completed

→ If blood draw is difficult with poor volume delivery, repeat draw 5 minutes later; record time on Specimen Collection Form and tube. If blood draw is impossible, repeat with new venipuncture.

↓

Following each blood draw: gently invert tube 5-10 times → Stand SST upright at room temp for 30 minutes, but no longer than 1 hour → Centrifuge at MAX SPEED between 1100-1300 g for 10 minutes in swinghead or 15 minutes in fixed angle*

↓

Transfer serum into the cryovial labeled "Iohexol Serum."

↓

Following packaging and shipping instructions; send urine, blood and copies of completed shipping form(s) & confirmation of written consent to CBL

**Physician should be immediately available (in person or by phone) during Iohexol Infusion**
**Encourage fluids throughout the visit.**

*1100-1300 g = 3000 rpm with 10 cm radius rotor

# SPECIMEN COLLECTION FORM for Visit 1a (L01)

F1. IOHEXOL INFUSION

a. INFUSION START TIME: ____ ____ : ____ ____ 1 = AM 2 = PM

- **DO NOT DRAW BLOOD FROM THE IV SITE WHERE IOHEXOL WAS INFUSED. ANOTHER IV SITE MUST BE USED.**
- **WASTE 1 mL OF BLOOD IF DRAWING FROM A SALINE/HEPARIN LOCK (OR PER DEVICE GUIDELINES).**
- **COLLECT 1 mL OF BLOOD FOR EACH IOHEXOL BLOOD DRAW IN THE PROVIDED SST.**
- **RECORDING THE EXACT NUMBER OF MINUTES ON THE TIMER IS MORE IMPORTANT THAN DRAWING THE BLOOD EXACTLY AT 120 & 300 MINUTES AFTER IOHEXOL INFUSION. FOR EXAMPLE, IF BLOOD IS DRAWN AT 133 MINS INSTEAD OF 120 MINS, DOCUMENT BLOOD DRAWN @ 133 MINS.**
- **TIME SHOULD BE RECORDED IMMEDIATELY AFTER EACH BLOOD SAMPLE IS OBTAINED (i.e., B1, B2).**

**POST VITALS SHOULD BE TAKEN 10 MINUTES AFTER INFUSION**
**USING LOCAL BLOOD PRESSURE MEASUREMENT (i.e. DINAMAP)**

- **If rash develops after Iohexol Infusion, consider it a reaction to Iohexol and notify PI immediately. Consider administration of 1 mg/kg Benadryl IV (maximum dose: 50 mg Benadryl IV).**
- **In the rare event that systolic BP decreases more than 25 mm Hg, diastolic BP decreases more than 20 mmHg, or pulse increases more than 20 beats per min, notify PI immediately to evaluate reaction and complete the Adverse Event (ADVR) Form. Consider the possibility of an anaphylactic reaction to Iohexol. Consider administration of 1 mg/kg Benadryl IV (maximum dose: 50 mg Benadryl IV). Draw up to 0.1 mL 1:1000 Epinephrine for SQ injection and 2 mg/kg Solumedrol IV for administration as ordered by physician.**

| **(i) Post Vitals:** | | |
|---|---|---|
| F2a. | Post- infusion blood pressure: | ___ ___ ___ / ___ ___ ___ |
| b. | Post-infusion temperature: | ___ ___ ___ . ___<br>1 = ºC Typical range: **36.1 – 38.3**<br>2 = ºF Typical range: **94.5 – 100.6** |
| c. | Post-infusion number of heart beats per minute: | ___ ___ ___ |
| d. | Post-infusion respirations per minute: | ___ ___ |

# SPECIMEN COLLECTION FORM for Visit 1a (L01)

**INVERT TUBE 5-10 TIMES AFTER EACH BLOOD DRAW**
**LET SST TUBE STAND 30 MINUTES (BUT NO LONGER THAN 1 HOUR)**
**CENTRIFUGE AT MAX SPEED BETWEEN 1100-1300g (3000rpm with 10cm radius rotor) for 10 MINUTES IN SWING HEAD**
**OR 15 MINUTES IN FIXED ANGLE (BALANCE TUBES IN CENTRIFUGE)**

| | **ALL TIMES should be documented from the initial infusion time** | **(i) ACTUAL HOURS/ MINUTES on TIMER** | (ii) **ONLY** if Timer malfunctions, record Clock Time using the same clock used for G1a | **(iii) Difficult Blood Draw:** Yes | No | **(iv) Blood Drawn via Venipuncture** Yes | No | **(v) Blood Volume Collected (1 mL):** | **(vi) Centrifuged at Clinical Site:** Yes | No |
|---|---|---|---|---|---|---|---|---|---|---|
| F3a. | **B1 2 hrs** (120 min): | ___ **hr** ___ ___ mins | __ __ : __ __ 1 = AM 2 = PM | 1 **(Skip to b)** | 2 | 1 | 2 | ___ . ___ mL | 1 **(Skip to F4a)** | 2 **(Skip to F4a)** |
| b. | **B1** 2nd attempt: | ___ **hr** ___ ___ mins | __ __ : __ __ 1 = AM 2 = PM | 1 | 2 | 1 | 2 | ___ . ___ mL | 1 | 2 |
| F4a. | **B2 5 hrs** (300 min): | ___ **hr** ___ ___ mins | __ __ : __ __ 1 = AM 2 = PM | 1 **(Skip to b)** | 2 | 1 | 2 | ___ . ___ mL | 1 **(END FORM)** | 2 **(END FORM)** |
| b. | **B2** 2nd attempt: | ___ **hr** ___ ___ mins | __ __ : __ __ 1 = AM 2 = PM | 1 | 2 | 1 | 2 | ___ . ___ mL | 1 | 2 |

# SPECIMEN COLLECTION FORM for Visit 1b (L02)

## CKiD Chronic Kidney Disease in Children Cohort Study

### SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: 0 1 b

A3. FORM VERSION: **0 3 / 0 1 / 1 8**

A4. SPECIMEN COLLECTION DATE: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. FORM COMPLETED BY (INITIALS): ___ ___ ___

**The following sample should be collected.**

| Samples: | Shipped to: | Shipped: |
|---|---|---|
| **Serum** | **CBL** | **BATCHED (Ship in Jan, Apr, Jul or Oct)** |
| **Plasma** | **CBL** | **BATCHED (Ship in Jan, Apr, Jul or Oct)** |

**Please refer to questions 26 and 27 on the Eligibility Form to determine if genetic and/or biological consent was obtained.**

**Depending on the type of consent, the following samples may or may not be collected:**

| Samples: | Shipped to: | Shipped: |
|---|---|---|
| **Whole Blood (Genetic)** | **NIDDK Biorepository** | **IMMEDIATELY** |
| **Nail Clippings (Biological)** | **NIDDK Biorepository** | **IMMEDIATELY** |
| **Hair (Biological)** | **NIDDK Biorepository** | **IMMEDIATELY** |
| **Serum (Biological)** | **NIDDK Biorepository** | **Batched (Jan, Apr, Jul or Oct)** |
| **Plasma (Biological)** | **NIDDK Biorepository** | **Batched (Jan, Apr, Jul or Oct)** |
| **Urine (Biological)** | **NIDDK Biorepository** | **Batched (Jan, Apr, Jul or Oct)** |

**BATCHED SAMPLES SHOULD BE SHIPPED QUARTERLY (Jan, Apr, July or Oct) OR MORE OFTEN IF DESIRED BY THE SITE COORDINATOR!**

**Samples should NOT be stored for more than one year.**
**For specific questions, contact your CCC prior to shipment.**

# SPECIMEN COLLECTION FORM for Visit 1b (L02)

## SECTION B: Visit V1B BLOOD DRAW

**For Initial Blood Draw with Syringe, Vacutainer OR Butterfly Method:**

**Select the Type of Consent Obtained (options 1 through 4) That Pertains to the CKiD Participant:**

**1**

**If participant consented to both BIOLOGICAL AND GENETIC samples:**

Collect 15 mL if participant is **< 30 kg** **OR** 19 mL if participant is **≥ 30 kg**.

If **< 30 kg**, immediately transfer **(using 18 gauge needle)** or draw:

- 6 mL into (1) 6mL ACD tubes for Genetic sample (**ACD Tube must be COMPLETELY FILLED**)
- 5 mL into (1) Tiger-Top SST for CBL and NIDDK Biorepository
- 4 mL into two (2) PSTs for CBL and NIDDK Biorepository

If **≥ 30 kg**, immediately transfer **(using 18 gauge needle)** or draw:

- 6 mL into (1) 6mL ACD tubes for Genetic sample **(ACD Tube must be COMPLETELY FILLED)**
- 7 mL into (1) Tiger-Top SST for CBL and NIDDK Biorepository
- 6 mL into two (2) PSTs for CBL and NIDDK Biorepository

**2**

**If participant consented to BIOLOGICAL samples ONLY:**

Collect 9 mL if participant is **< 30 kg** **OR** 13 mL if participant is **≥ 30 kg**.

If **< 30 kg**, immediately transfer or draw:

- 5 mL into (1) Tiger-Top SST for CBL and NIDDK Biorepository
- 4 mL into two (2) PSTs for and CBL NIDDK Biorepository

If **≥ 30 kg**, immediately transfer or draw:

- 7 mL into (1) Tiger-Top SST for CBL and NIDDK Biorepository
- 6 mL into two (2) PSTs for CBL and NIDDK Biorepository

**3**

**If participant consented to GENETIC samples ONLY:**

Collect 9 mL from all participants (regardless of weight)

Immediately transfer or draw:

- 6 mL into (1) 6mL ACD tube for Genetic sample (ACD Tubes must be COMPLETELY FILLED)
- 2 mL into (1) Tiger-Top SST for CBL
- 1 mL into (1) PST for CBL

**4**

**If participant did NOT consent to BIOLOGICAL AND GENETIC samples:**

Collect 3 mL from all participants (regardless of weight). Immediately transfer or draw 2 mL into (1) Tiger-Top SST for CBL and 1mL into PST for CBL.

## SECTION B: Visit 1B BLOOD DRAW PROCESSING
## PROCESSING BLOOD FOR CBL AND NIDDK BR SAMPLES

### CBL & NIDDK BR (Serum)

Invert the Tiger Top SST 5 times gently to mix.

Stand SST upright to allow clotting at room temperature for 30 mins and not more than 1 hour (60 mins).

Centrifuge SST at MAX SPEED between 1100-1300g (3000rpm with 10cm radius rotor) for 10 mins in swinghead OR 15 mins in fixed angle. *If incomplete separation, centrifuge again 10-15 mins.

**NIDDK (Serum)**
Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) serum into clear top cryovial (use different pipettes for serum and plasma). **If there is any extra serum, then pipette the extra serum into the clear top cryovial marked "NIDDK BR SERUM".*

Store sample(s) in freezer at -70ºC or lower, batch up to 40 samples and ship during **January, April, July and October**. When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/. Then, follow packaging instructions.

**iPTH/hsCRP**
Pipette 0.5 mL of serum into red top cryovial tube for CBL iPTH &, hsCRP

**Vitamin D**
Pipette 0.5 mL of serum into red top cryovial for CBL Vitamin D

Store sample in freezer at -70ºC or lower and batch up to 20 samples and ship quarterly during the months of **January, April, July and October**. When shipper is needed, complete "CBL Dry Ice Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ Then, follow packaging instructions and ship to CBL with accompanying forms. No FRIDAY shipments. Refrigerate and ship on next business day.

### CBL & NIDDK BR (Plasma)

Invert each PST 8-10 times gently to mix.

Centrifuge each PST at MAX SPEED between 1100-1300g for 10 mins (swinghead) **OR** 15 mins (fixed angle).

**FGF-23**
Pipette 0.5 mL of plasma into a cryovial with a green cap insert for CBL FGF-23

Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) plasma into cryovial with green cap insert (use different pipettes for serum and plasma). **If there is any extra plasma, then pipette the extra plasma into the green cap insert cryovial marked "PLASMA (Extra)".*

Store sample(s) in freezer at -70ºC or lower, batch up to 40 samples and ship during the months of **January, April, July and October**. When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/. Then, follow packaging instructions.

### NIDDK BR (Whole Blood for DNA)

Invert ACD Tube 6 times gently to mix blood with additives.

Keep tube at room temperature. **DO NOT FREEZE.**

Follow packaging instructions, complete DNA Collection Form and ship immediately to NIDDK Biorepository with accompanying forms. **Specimen can be shipped on Friday.**

Complete "On-line Shipping Form" on CKiD website to notify KIDMAC that sample(s) have been shipped.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ to notify the appropriate personnel from the CBL and the NIDDK BR.

## SECTION B: Visit 1B BLOOD DRAW AND PROCESSING

B1. ACTUAL TIME OF BLOOD DRAW ____ ____ : ____ ____ 1 = AM 2 = PM

| **Reasons Code List*:** | 1= Not required | 4 = Red Blood Cell Contamination | 7 = Exceed maximum allowable volume |
|---|---|---|---|
| | 2 = Difficult Blood Draw | 5 = Inadvertently Destroyed | |
| | 3 = Participant Refused | 6 = Oversight | |

| **Sample Type (Required Volume in Top Color Tube Type):** | **(a) Sample Obtained:** Yes | No | **(b) If No, specify reason *SEE CODE LIST ABOVE** | **(c) Additional Requirements:** |
|---|---|---|---|---|
| B2a. Serum for iPTH, hsCRP & Vitamin D (2.0 mL of blood in Tiger Top SST) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to B2b)** | Date Frozen: ___ ___ /___ ___ /___ ___ ___ ___ M M D D Y Y Y Y |
| B2b. Plasma for FGF-23 (1.0 mL of blood in PST) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to B3)** | Date Frozen: ___ ___ /___ ___ /___ ___ ___ ___ M M D D Y Y Y Y |

B3. Did the participant consent to have whole blood stored at NIDDK Biorepository?
Yes..... 1
No..... 2 **(Skip to B5)**

| **Sample Type (Required Volume in Top Color Tube Type):** | **(a) Sample Obtained:** Yes | No | **(b) If No, specify reason *SEE CODE LIST ABOVE** | **(c) Additional Requirements:** |
|---|---|---|---|---|
| B4. Whole Blood for NIDDK Biorepository (6 mL of blood in 1 (6 mL) ACD tube) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to B5)** | i. Date of Blood Draw: ___ ___ /___ ___ /___ ___ ___ ___ M M D D Y Y Y Y<br>ii. Blood Drawn By : ____ ____ (initials)<br>iii. Gender of participant : Male.....1 Female.....2<br>iv. Age of participant : ____ ____ years |

B5. Did the participant consent to have biological samples (i.e., serum, plasma, urine, nail clippings and hair samples) stored at NIDDK Biorepository?

Yes..... 1

No..... 2 **(END)**

| **Reasons Code List*:** | 1= Not required | 4 = Red Blood Cell Contamination | 7 = Exceed maximum allowable volume |
|---|---|---|---|
| | 2 = Difficult Blood Draw | 5 = Inadvertently Destroyed | |
| | 3 = Participant Refused | 6 = Oversight | |

| **Sample Type (Required Volume in Top Color Tube Type):** | **(a) Sample Obtained:** Yes / No | **(b) If No, specify reason *SEE CODE LIST ABOVE** | **(c) Additional Requirements:** |
|---|---|---|---|
| B6. Serum for NIDDK Biorepository (**3.0 mL or **5.0 mL of blood in Tiger Top SST) | 1 **(skip to c→)** / 2 | __ __ **(skip to B7)** | Date Frozen: __ __ /__ __ /__ __ __ __ M M D D Y Y Y Y |
| B7. Plasma for NIDDK Biorepository (**3.0 mL of blood (1) Green Top or **5.0 mL (2) Green Top PSTs) | 1 **(skip to c→)** / 2 | __ __ **(skip to C1)** | Date Frozen: __ __ /__ __ /__ __ __ __ M M D D Y Y Y Y |

** Collect 3.0 mL of whole blood for participants < 30 kg and 5.0 mL for participants ≥ 30 kg

## SECTION C: Visit 1B URINE COLLECTION AND PROCESSING FOR REPOSITORY

Collect FRESH urine into an initial urine collection cup or hat (provided by the site).

Pour 15-60 mL (preferably 60 mL) of FRESH urine into 90 mL urine collection cup with 4 protease inhibitor tablets. Do not fill the urine past the 60 mL mark on the collection cup. One protease inhibitor tablet should be used for 10-15 mL of urine **(see Table A)**. For example if 30 mL of urine is collected, ONLY 2 PI tablets are needed. (Like all unused supplies, **unused protease inhibitor tablets should be returned to the CBL**.)

**TABLE A:**

| Urine Volume | # of Protease Inhibitor Tablets |
|---|---|
| 10 – 15 mL | **1** |
| 16 – 30 mL | **2** |
| 31 – 45 mL | **3** |
| 46 – 60 mL | **4** |

Invert the urine cup gently 5 – 10 times.

The PROTEASE INHIBITOR TABLET(s) MUST BE **COMPLETELY** DISSOLVED in the urine.

Once the protease inhibitor tablet(s) are completely dissolved, pour urine into up to six (6) 10 mL urine centrifuge tubes.
(**For each tube:** remove yellow top cap, pour urine into tube and SCREW cap back onto tube.) Place no more than 10 mL in each tube.
**-- OR –**
**Sites may also substitute with tubes normally used to centrifuge urine at site.**

Centrifuge urine tube(s) at MAX SPEED between 1100-1300g (3000rpm with 10cm radius rotor) for 10 mins (swinghead units) **– OR –** 15 mins (fixed angle units).

Decant (pour off) the supernates (liquid reaction) into up to seven (7) 10 mL urine cryovials. Pour no more than 9 mL of urine into each 10 mL cryovial to allow for expansion.

Check that all information is correct on the urine cryovials, promptly freeze and store sample(s) at -70ºC or lower. Batch samples and ship at least quarterly (include maximum of 36 cryovials per shipper). When shipper(s) is needed, complete *"NIDDK Shipper Request Form"* on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/. Then, follow packaging instructions.

When pickup has been scheduled, complete *"Online Shipping Form"* on CKiD website to notify the NIDDK and KIDMAC that sample(s) have been shipped to NIDDK BR.

**Reasons Code List*:** 1= Not required | 2 = Difficult Urine Collection | 3 = Participant Refused | 4 = Collection Contamination | 5 = Inadvertently Destroyed | 6 = Oversight | 7 = Insufficient volume

| Sample Type (Required Volume in Top Color Tube Type): | (a) Sample Obtained: Yes | (a) Sample Obtained: No | (b) If No, specify reason *SEE CODE LIST ABOVE | (c) Additional Requirements: |
|---|---|---|---|---|
| C1. Urine for NIDDK Biorepository (15.0 - 60.0 mL of urine in specimen container and transferred into collection cup with protease inhibitors) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to D1)** | i. Was supernate decanted into urine transport cryovials? Yes.....1 No.....2<br>ii. Date Frozen: ___ ___ /___ ___ /___ ___ ___ ___ (M M D D Y Y Y Y) |

## SECTION D: NAIL CLIPPING COLLECTION

- Collection of fingernails is preferred. **DO NOT** collect fingernail clippings if the participant has acrylic nails, nail fungus, or discoloration causing pain or discomfort. If the participant cannot provide fingernail clippings, the Study Coordinator may clip the participant's toenails instead. **FINGERNAILS AND TOENAILS SHOULD <u>NOT</u> BE COLLECTED IN THE SAME CRYOVIAL** (collect one or the other).
- STAINLESS STEEL NAIL CLIPPERS MUST BE USED TO COLLECT NAIL CLIPPINGS. Use small (pediatric size) stainless steel nail clippers (see Figure A) for younger participants and large stainless steel nail clippers (see Figure B) for older participants. Both sizes are included in the CKiD starter package.

➢ Clean the blades of the nail clippers with **SaniZide Plus** prior to use (provided by the CBL).


➢ Whenever possible, the Study Coordinator should clip all (10) fingernails, removing approximately 1 millimeter from each nail (See Figure C). **Be prepared to collect flyaway nails.**
➢ (To use nail clippers, see Figures A – D). Refer to CKiD MOP Section 12 for further details.
➢ Carefully place the nail clippings into the cryovial (see Figure D). After using the nail clipper, spray the clipper with **SaniZide Plus** and wipe clean with clean cloth.

**Figure A**

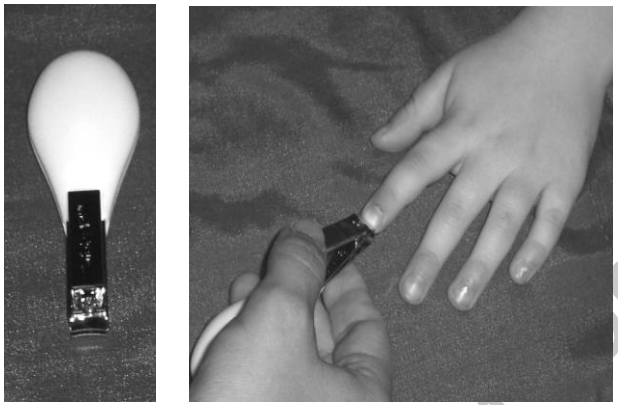


**Figure B**

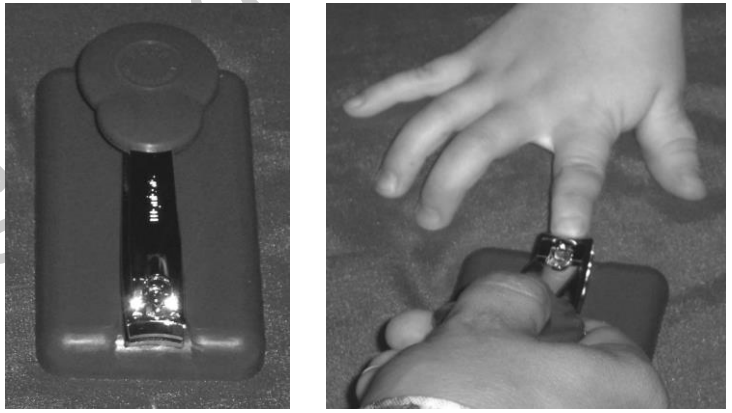
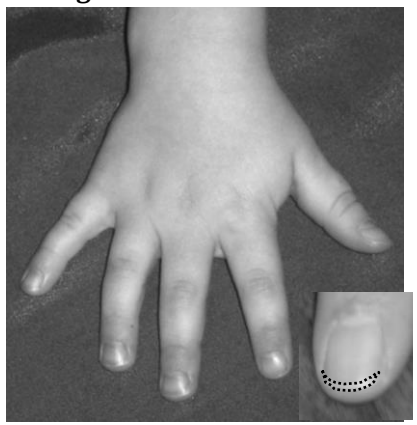


**Figure C**



Provide 10 nail clippings that are at least 1 mm tall

**Figure D**

D1. Does the participant have acrylic nails?

Yes..... 1 **(Skip to D3)**

No..... 2

D2. Were 10 fingernail clippings collected?

Yes..... 1 **(Skip to E1)**

No..... 2

a. How many fingernail clippings were collected?

___ ___

b. Specify reason "10" fingernail clippings were not collected.

Nails not long enough..... 1 **(Skip to D3)**

Participant Refused..... -7 **(Skip to D3)**

Other..... 2

i. Specify:_____

_____

D3. Were 10 toenail clippings collected?

Yes..... 1 **(Skip to E1)**

No..... 2

a. How many toenail clippings were collected?

___ ___

b. Specify reason "10" toenail clippings were not collected: (e.g., Nail fungus or discoloration causing pain or discomfort)

Nail fungus or discoloration..... 1 **(Skip to E1)**

Nails not long enough..... 2 **(Skip to E1)**

Participant Refused..... -7 **(Skip to E1)**

Other..... 3

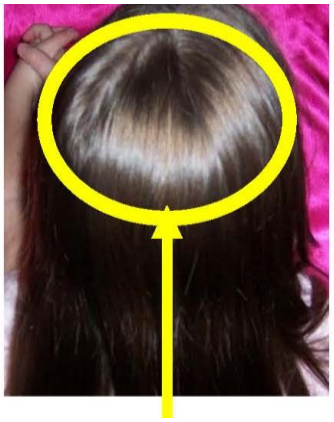
i. Specify: _____

_____

## SECTION E: HAIR SAMPLE COLLECTION

- STAINLESS STEEL SCISSORS MUST BE USED TO COLLECT HAIR SAMPLE. The scissors are included in the CKiD starter package.
- DO NOT collect hair sample if the participant has colored, or chemically altered hair
- Clean blades of stainless steel scissors with **SaniZide Plus** prior to use.
- Use powder-free gloves.
- Refer to CKiD MOP Section 12 for further details.
  - Lift up the top layer of hair from the **occipital** region of the scalp (see Figure A). Isolate a small thatch of hair (at least 20 fibers) from this region (see Figure B).
  - **Place the label with the participant's KID ID # tightly around all 20 strands of hair located at the distal end (furthest from the scalp)** (see Figure C).
  - Cut the hair sample off the participant's head **as close to the scalp as possible** (see Figure D).
  - Place cut thatch of hair inside aluminum foil (4 X 4) and fold the top of the foil to completely enclose the hair sample.
  - Place the aluminum foil inside a Ziplock bag (4 X 4) with the gel desiccant pellets in it and seal.
  - Store sample at room temperature in a dark place prior to shipment.
  - After using the scissors, spray scissors with **SaniZide Plus** and wipe clean with clean cloth**.**


**Figure A**



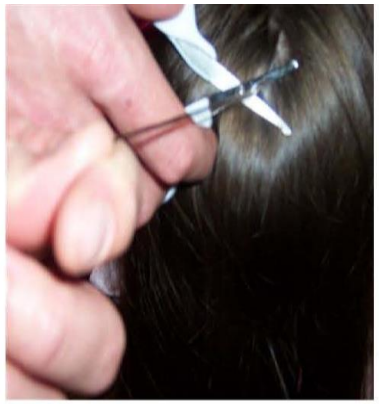
**Occipital Region of Scalp**

**Figure B**

**Figure C**

**Place the KID ID label tightly around all 20 strands.**

**Figure D**



**Cut the hair sample off the participant's head *as close to the scalp as possible.***

E1. Does the participant have permed, dyed, colored, or chemically altered hair?

Yes..... 1 **(End Form)**

No..... 2

E2. Was the Study Coordinator able to cut at least 20 fibers of hair from the **occipital** region?

Yes..... 1 **(End Form)**

No..... 2

a. Specify reason "20" hair fibers were not collected:

Hair not long enough..... 1 **(End Form)**

Participant Refused..... -7 **(End Form)**

Other..... 2

i. Specify: _____

_____

# SPECIMEN COLLECTION FORM for Visit 2 (L21)

## CKiD Chronic Kidney Disease in Children Cohort Study

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: ___ ____

A3. FORM VERSION: **0 3 / 0 1 / 1 8**

A4. SPECIMEN COLLECTION DATE: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. FORM COMPLETED BY (INITIALS): ___ ___ ___

**The following samples should be collected.**

| Samples: | Shipped to | Shipped: |
|---|---|---|
| **Serum** | **CBL** | **IMMEDIATELY** |
| **Serum** | **CBL** | **Batched (Ship in Jan, Apr, Jul or Oct)** |
| **Urine** | **CBL** | **IMMEDIATELY** |
| **Iohexol Blood*** | **CBL** | **IMMEDIATELY** |

*** COLLECT IOHEXOL BLOOD DRAW: Only if Cohort 3 participants who consent to iohexol protocol or Cohorts 1 & 2 participants had previous iGFR>90**

**If consent is obtained for biological samples, collect the following:**

| Samples: | Shipped to: | Shipped: |
|---|---|---|
| **Serum (Biological)** | **NIDDK Biorepository** | **Batched (Ship in Jan, Apr, Jul or Oct)** |
| **Plasma (Biological)** | **NIDDK Biorepository** | **Batched (Ship in Jan, Apr, Jul or Oct)** |
| **Urine (Biological)** | **NIDDK Biorepository** | **Batched (Ship in Jan, Apr, Jul or Oct)** |
| **Nail Clippings (Biological)** | **NIDDK Biorepository** | **IMMEDIATELY** |
| **Hair (Biological)** | **NIDDK Biorepository** | **IMMEDIATELY** |

**BATCHED SAMPLES SHOULD BE SHIPPED QUARTERLY (Jan, Apr, July or Oct) OR MORE OFTEN IF DESIRED BY THE SITE COORDINATOR!**

**Samples should NOT be stored for more than one year.**
**For specific questions, contact your CCC prior to shipment.**

# SECTION B: PREGNANCY TEST AND FIRST MORNING URINE COLLECTION

B1. Is participant a female of child-bearing potential?

Yes..... 1 **(See PROMPT Below)**
No..... 2 **(Skip to B3)**

***PROMPT: QUESTION B2 IS FOR FEMALE PARTICIPANTS OF CHILD-BEARING POTENTIAL ONLY. URINE PREGNANCY TEST DATE MUST FALL WITHIN 72 HOURS BEFORE STUDY VISIT DATE.***

***If performing iohexol protocol, B2 MUST BE COMPLETED BEFORE IOHEXOL TESTING IS INITIATED.***

B2. a. Urine pregnancy test date: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

b. Urine pregnancy results:

Positive..... 1 **(END; COMPLETE TRANSITIONAL (TRS01) FORM)**
Negative..... 2

# FIRST MORNING URINE COLLECTION

Obtain urine collected at home in the specimen container that was shipped to the family before the visit.
IF URINE WAS NOT collected at home, collect FRESH urine sample during CKiD visit.

(Refer to MOP Section 11 and/or CBL flowchart for additional information and directions)

Pour at least1 mL of urine into the CBL transport tube.

↓

Check that all information is correct on the urine collection tube and follow packaging instructions and ship to CBL.

| **Reasons Code List*:** | 1= Not required | 4 = Collection Contamination | 7 = Insufficient Volume |
|---|---|---|---|
| | 2 = Difficult Urine Collection | 5 = Inadvertently Destroyed | |
| | 3 = Participant Refused | 6 = Oversight | |

| **Sample Type (Required Volume):** | **(a) Sample Obtained:** Yes / No | **(b) If No, specify reason** *SEE CODE LIST ABOVE | **(c) Additional Requirements:** |
|---|---|---|---|
| B3. Urine Creatinine, Urine Protein, Urine Albumin (CBL) (1.0 mL–10 mL) | 1 / 2 **(skip to c→)** | ___ ___ **(skip to C1)** | i. Is this a first morning urine sample? Yes.....1 No.....2 |
| | | | ii. Time of Collection: __ __ : __ __ 1 = am, 2 = pm |

# SPECIMEN COLLECTION FORM for Visit 2 (L21)

## SECTION C: Visit 2 BLOOD DRAW

**For Initial Blood Draw with Syringe, Vacutainer OR Butterfly Method: Select the Type of Consent Obtained (options 1 through 3):**

**1** **If participant consented to BIOLOGICAL samples:**
Collect **14-15** mL if participant is **< 30 kg** **OR** **20-21** mL if participant is **≥ 30 kg**.

If **< 30 kg**, immediately transfer **(using 18 gauge needle)** or draw:
- 8.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK Biorepository
- 3 mL into (1) PST for NIDDK Biorepository
- 1 mL in lavender-top tube for local CBC *(tube not provided in CBL kit)*
- 1.5 mL in appropriate tube *(not provided)* for local Renal Panel
- ***1 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)***

If **≥ 30 kg**, immediately transfer **(using 18 gauge needle)** or draw:
- 12.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK Biorepository
- 5 mL into (2) PST for NIDDK Biorepository
- 1 mL in lavender-top tube for local CBC *(tube not provided in CBL kit)*
- 1.5 mL in appropriate tube *(not provided)* for local Renal Panel
- ***1 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)***

**2** **If participant did NOT consent to BIOLOGICAL samples:**
Collect **5-6** mL from all participants (regardless of weight) as specified below.

Immediately transfer (using 18 gauge needle) or draw:
- 2.5 mL into (1) Tiger-Top SSTs for CBL
- 1 mL in lavender-top tube for local CBC *(tube not provided in CBL kit)*
- 1.5 mL in appropriate tube *(not provided)* for local Renal Panel
- ***1 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)***

**3** **For Participant Completing Iohexol Study Visit**
Only Cohort 3 participants who consent to iohexol protocol or Cohorts 1 & 2 participants with previous iGFR>90

For IOHEXOL study visits:
- ***1mL of additional blood into Tiger Top SST for CBL Iohexol Blank (B0) blood sample***

Iohexol is infused at the time of initial blood draw.
Refer to page 10 for **Instructions for Iohexol Infusion and GFR Blood Draws.**

## SECTION C: Visit 2 BLOOD DRAW PROCESSING

Invert the SST 5 times & PST 8-10 times gently to mix.

Stand SST upright to allow clotting at room temperature for 30 mins and not more than 1 hour (60 mins).

Centrifuge SST & PST at MAX SPEED between 1100-1300g (3000rpm with 10cm radius rotor) for 10 minutes in swinghead units **OR** 15 minutes in fixed angle units (balance tube in centrifuge).*If incomplete separation, centrifuge again for 10-15 minutes.

**If sample is GROSSLY HEMOLYZED.**

You must send hemolyzed sample to CBL. If participant has eaten, aliquot hemolyzed sample for fasting lipid profile and send to CBL. Also, if the sample is **GROSSLY HEMOLYZED (Dark Red),** collect 1 mL of additional blood in a SST. Centrifuge and then transfer serum into the extra Orange Top Transport Tube provided.

**If sample is moderately, slightly or NOT HEMOLYZED, proceed with CBL and NIDDK BR preparation.**

**For IOHEXOL STUDY VISITS ONLY:**
**B0 sample**

Using the disposable pipette, pipette 0.5 mL of serum into Round-bottom Orange Top Transport Tube labeled "B0" for Iohexol Blank (B0) sample. Follow packaging instructions and ship to CBL with accompanying forms, iohexol blood draws and urine. **No FRIDAY shipments.** Refrigerate specimen and ship on next business day.

**CBL Studies**

Using the disposable pipette, pipette 0.75 mL of serum into Orange Top Transport Tube labeled "Serum CBL" for CBL renal/uric acid and lipids. Follow packaging instructions and ship to CBL with accompanying forms, iohexol blood draws and urine. **No FRIDAY shipments.** Refrigerate specimen and ship on next business day.

**Cystatin C**

Using the disposable pipette, pipette 0.5 mL of serum into Blue Screw-Top Cryovial for Cystatin C. Store sample in freezer at -70°C or lower, batch up to 20 samples and ship on dry ice every four months to the CBL. When shipper is needed, complete "CBL Dry Ice Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ Then, follow packaging instructions and ship to CBL with accompanying forms. **No FRIDAY shipments.** Ship on next business day.

**NIDDK BR (Serum & Plasma)**

Pipette 3 mL (<30kg) or 5 mL (≥ 30kg) of serum into clear top cryovial & 1.5 mL (<30kg) or 2.5 mL (≥ 30kg) of plasma into cryovial into green cap insert (use different pipettes for serum and plasma).
**If there is any extra serum and/or plasma, then pipette the extra serum into the clear top cryovial marked "NIDDK BR SERUM" and the extra plasma in green cap insert cryovial marked "PLASMA (Extra)."*
Store samples in freezer at -70°C or lower, & batch up to 40 samples and ship on dry ice in January, April, July or October to the NIDDK BR. When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/. Then, follow packaging instructions.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ to notify the appropriate personnel from the CBL and the NIDDK BR.

# SPECIMEN COLLECTION FORM for Visit 2 (L21)

C1. ACTUAL TIME OF BLOOD DRAW ____ ____ : ____ ____ 1 = AM 2 = PM

***PROMPT: IF SUSPECTED BLOOD DRAW ADVERSE EVENT (i.e., infection), complete ADVERSE EVENT (ADVR) Form***

| **Reasons Code List*:** | | | |
|---|---|---|---|
| | 1= Not required | 4 = Red Blood Cell Contamination | 7 = Exceed maximum allowable volume |
| | 2 = Difficult Blood Draw | 5 = Inadvertently Destroyed | |
| | 3 = Participant Refused | 6 = Oversight | |

| **Sample Type (Required Volume in Top Color Tube Type):** | **(a) Sample Obtained:** Yes | No | **(b) If No, specify reason** ***SEE CODE LIST ABOVE** | **(c) Additional Requirements:** |
|---|---|---|---|---|
| C2. Renal/Uric Acid Chemistries (2.0 mL in Tiger Top SST) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to C3)** | **Indicate the appearance of the serum after centrifuging.** Grossly (Dark Red).....1 Moderately (Red/Light Red).....2 Slightly (Pink)..... .....3 Not Hemolyzed (Yellow).....4 |
| C3. Cystatin C (1.0 mL in Tiger Top SST) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to C4a)** | Date Frozen: ___ ___ /___ ___ /___ ___ ___ ___ M M D D Y Y Y Y |
| C4a. Local CBC (1.0 mL in Lavender Top tube) | 1 **(skip to C4b)** | 2 | ___ ___ **(skip to C4b)** | **N/A** |
| C4b. Local Renal Panel (1.5 mL in Local SST) | 1 **(skip to C5)** | 2 | ___ ___ **(skip to C5)** | **N/A** |
| C5. Serum for Fasting Lipid Panel (0.5 mL in Tiger Top SST) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to C6)** | **Did the participant fast after midnight?** Yes…….....1 No…….....2* |

*If the participant did not fast, the Nephron Lipid Report will indicate that the participant did not fast.

Sites can obtain results for lab values that have been identified as “KEY VARIABLES”. To obtain results, go the CKiD Nephron Website: **https://statepiaps8.jhsph.edu/nephron/groups/aspproc/**, click on “Report Menu” and choose the appropriate lab report (i.e., Selected Renal Panel Lab Variables Report.)

C6. Did the participant consent to have biological samples (i.e., serum, plasma and urine samples) stored at the NIDDK Biorepository?

Yes..... 1

No..... 2 **(Skip to E2)**

| **Reasons Code List*:** | 1= Not required | 4 = Red Blood Cell Contamination | 7 = Exceed maximum allowable volume |
|---|---|---|---|
| | 2 = Difficult Blood Draw | 5 = Inadvertently Destroyed | |
| | 3 = Participant Refused | 6 = Oversight | |

| **Sample Type (Required Volume in Top Color Tube Type):** | **(a) Sample Obtained:** Yes / No | **(b) If No, specify reason *SEE CODE LIST ABOVE** | **(c) Additional Requirements:** |
|---|---|---|---|
| C7. Serum for NIDDK Biorepository (**6.0 mL or **10.0 mL of blood in Tiger Top SST) | 1 **(skip to c→)** / 2 | __ __ **(skip to C8)** | Date Frozen: __ __ /__ __ /__ __ __ __ M M D D Y Y Y Y |
| C8. Plasma for NIDDK Biorepository (***3.0 mL of blood in one Green Top or ***5.0 mL in two Green Top PSTs) | 1 **(skip to c→)** / 2 | __ __ **(skip to D1)** | Date Frozen: __ __ /__ __ /__ __ __ __ M M D D Y Y Y Y |

** Collect 6.0 mL of whole blood for participants < 30 kg and 10.0 mL for participants ≥ 30 kg

*** Collect 3.0 mL of whole blood for participants < 30 kg and 5.0 mL for participants ≥ 30 kg

# SPECIMEN COLLECTION FORM for Visit 2 (L21)

## SECTION D: URINE COLLECTION AND PROCESSING FOR REPOSITORY

Collect FRESH urine into an initial urine collection cup or hat (provided by the site).

Pour 15-60 mL (preferably 60 mL) of FRESH urine into 90 mL urine collection cup with 4 protease inhibitor tablets. Do not fill the urine past the 60 mL mark on the collection cup. One protease inhibitor tablet should be used for 10-15 mL of urine **(see Table A)**. For example if 30 mL of urine is collected, ONLY 2 PI tablets are needed. (Like all unused supplies, **unused protease inhibitor tablets should be returned to the CBL**.)

**TABLE A:**

| Urine Volume | # of Protease Inhibitor Tablets |
|---|---|
| 10 – 15 mL | **1** |
| 16 – 30 mL | **2** |
| 31 – 45 mL | **3** |
| 46 – 60 mL | **4** |

Invert the urine cup gently 5 – 10 times.

The PROTEASE INHIBITOR TABLET(s) MUST BE **COMPLETELY** DISSOLVED in the urine.

Once the protease inhibitor tablet(s) are completely dissolved, pour urine into up to six (6) 10 mL urine centrifuge tubes.
(**For each tube:** remove yellow top cap, pour urine into tube and SCREW cap back onto tube.) Place no more than 10 mL in each tube.
**-- OR –**
**Sites may also substitute with tubes normally used to centrifuge urine at site.**

Centrifuge urine tube(s) at MAX SPEED between 1100-1300g (3000rpm with 10cm radius rotor) for 10 mins (swinghead units) **– OR –** 15 mins (fixed angle units).

Decant (pour off) the supernates (liquid reaction) into up to seven (7) 10 mL urine cryovials. Pour no more than 9 mL of urine into each 10 mL cryovial to allow for expansion.

Check that all information is correct on the urine cryovials, promptly freeze and store sample(s) at -70ºC or lower. Batch samples and ship at least quarterly (include maximum of 36 cryovials per shipper). When shipper(s) is needed, complete *"NIDDK Shipper Request Form"* on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/. Then, follow packaging instructions.

When pickup has been scheduled, complete *"Online Shipping Form"* on CKiD website to notify the NIDDK BR and KIDMAC that sample(s) have been shipped to NIDDK BR.

**Reasons Code List*:** 1= Not required | 2 = Difficult Urine Collection | 3 = Participant Refused | 4 = Collection Contamination | 5 = Inadvertently Destroyed | 6 = Oversight | 7 = Insufficient volume

| Sample Type (Required Volume in Top Color Tube Type): | (a) Sample Obtained: Yes | (a) Sample Obtained: No | (b) If No, specify reason *SEE CODE LIST ABOVE | (c) Additional Requirements: |
|---|---|---|---|---|
| D1. Urine for NIDDK Biorepository (15.0 - 60.0 mL of urine in specimen container and transferred into collection cup with protease inhibitors) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to E2)** | i. Was supernate decanted into urine transport cryovials? Yes.....1 No.....2<br>ii. Date Frozen: ___ ___ /___ ___ /__ ___ ___ ___ (M M D D Y Y Y Y) |

## SECTION E: OPTIONAL TESTS

## LOCAL LAB TEST (IF CLINICALLY INDICATED)

Check with the PI at your clinical site to determine whether or not it is **CLINICALLY INDICATED** to obtain urine for local lab. These are instances when the PI needs results immediately and/or the participant needs additional local labs performed (i.e., local Urine Creatinine and Urine Protein).

E2. Was a urine protein to creatinine ratio assay performed at the clinical site's local laboratory?

Yes..... 1 → **Complete Local Urine Assay Results Form L06, ONLY if local labs are CLINICALLY INDICATED**

No..... 2

## IOHEXOL PROTOCOL

E3. Is the participant completing iohexol study visit?

Yes, consent obtained..... 1

No..... 2 → **(Skip to Section H)**

## ONLY COMPLETE SECTIONS F & G IF PARTICIPANT IS COMPLETING IOHEXOL STUDY VISIT.

**Only Cohort 3 participants who consent to iohexol protocol or Cohorts 1 & 2 participants with previous iGFR>90 should complete iohexol protocol. If you have additional questions, contact CCC.**
**For an iohexol study visit, additional blood (including blood for the Iohexol "B0" Blank sample) should be collected for Iohexol-Based GFR.**

## SECTION F: INFUSION SYRINGE WEIGHT

F1. **SCALE MUST FIRST BE ZEROED BEFORE WEIGHING. REMOVE ALUMINUM FOIL PRIOR TO WEIGHING THE SYRINGE. THE SAME SCALE MUST BE USED TO WEIGH THE SYRINGE PRE AND POST IOHEXOL INFUSION.**

a. Syringe Weight **Pre-Iohexol Infusion**: ___ ___ . ___ ___ (g)

b. Syringe Weight **Post-Iohexol Infusion**: ___ ___ . ___ ___ (g) (Post-Infusion Weight should be **at least 6.0g** less than Pre-Infusion Weight. If Post-Infusion Weight is not at least 6g less, please confirm.)

## PRE AND POST SYRINGE WEIGHT MUST BE OBTAINED IN ORDER TO CALCULATE PARTICIPANT'S GFR.

## SECTION G: IOHEXOL – Refer to Instructions for Iohexol Infusion and GFR Blood Draws Flow Chart on Page 10

- **BEFORE** INFUSING **5 mL OF** IOHEXOL, **SET TIMER = 0**. SIMULTANEOUSLY START TIMER AND BEGIN IOHEXOL INFUSION
- **COMPLETE INFUSION BETWEEN 1 TO 2 MINS**
- LEAVE TIMER RUNNING THROUGHOUT IOHEXOL INFUSION AND SUBSEQUENT BLOOD DRAWS

## Instructions for Iohexol Infusion and GFR Blood Draws

Place two IV lines (18-22 gauge polyethylene catheters) using two separate vascular access sites
---OR---
Place one butterfly and one IV line (18-22 gauge polyethylene catheter) using two separate vascular access sites; use tape to stabilize butterfly for iohexol infusion
--OR---
Use butterfly for pre-iohexol and individual blood draw sticks; use tape to stabilize butterfly for Iohexol infusion

↓

Complete pre-iohexol infusion blood draw according to instructions

↓

Start timer and infuse iohexol over 1-2 minutes
**If infusion site for iohexol IV or butterfly infiltrates, study MUST BE DISCONTINUED**
**Must wait at least 48 hours to repeat study, and repeat visit should occur within 3 months of initial**

↓

Flush with 10 mL normal saline to ensure infusion of all of the iohexol; **IOHEXOL IV OR BUTTERFLY MAY NOW BE REMOVED**

↓

**10 minutes post-infusion**
**CHECK POST-INFUSION VITALS**
**DO NOT DRAW BLOOD AT 10 MINUTES**

→ If rash develops, consider it a reaction to iohexol and **notify PI immediately**. Consider administering 1mg/kg Benadryl IV (maximum dose 50mg).

→ If systolic BP decreases > 25 mm Hg, diastolic BP decreases > 20 mm Hg or pulse increases > 20 beats per min, consider this an anaphylactic reaction to iohexol and **notify PI immediately**; consider administering 1 mg/kg Benadryl IV (maximum dose 50 mg) and draw up to 0.1 mL 1:1000 Epinephrine for SQ injection and 2 mg/kg Solumedrol IV if necessary.

↓

COMPLETE ADVERSE EVENT FORM and send to CCC for data entry

↓

Obtain post-infusion weight of syringe on the same scale as prior to infusion. Record weight on the Specimen Collection Form prior to shipment to the CCC

↓

Draw 1 ml of blood into SST at 120 mins (B1), and 300 mins (B2).

*For IV ONLY: Discard initial 1 mL blood waste at each blood draw (or per device guidelines)

*For IV ONLY: Flush after each blood draw with at least 3 mL normal saline

*Record the time each blood draw is completed

→ If blood draw is difficult with poor volume delivery, repeat draw 5 minutes later; record time on Specimen Collection Form and tube. If blood draw is impossible, repeat with new venipuncture.

↓

Following each blood draw: gently invert tube 5-10 times

→ Stand SST upright at room temp for 30 minutes, but no longer than 1 hour

→ Centrifuge at MAX SPEED between 1100-1300 g for 10 minutes in swinghead or 15 minutes in fixed angle*

↓

Transfer serum into the cryovial labeled "Iohexol Serum."

↓

Following packaging and shipping instructions; send urine, blood and copies of completed shipping form(s) & confirmation of written consent to CBL

**Physician should be immediately available (in person or by phone) during Iohexol Infusion**
**Encourage fluids throughout the visit.**
*1100-1300 g = 3000 rpm with 10 cm radius rotor





Chronic Kidney Disease in Children

G1. IOHEXOL INFUSION

a. INFUSION START TIME: ____ ____ : ____ ____ 1 = AM 2 = PM

- **DO NOT DRAW BLOOD FROM THE IV SITE WHERE IOHEXOL WAS INFUSED. ANOTHER IV SITE MUST BE USED.**
- **WASTE 1 mL OF BLOOD IF DRAWING FROM A SALINE/HEPARIN LOCK (OR PER DEVICE GUIDELINES).**
- **COLLECT 1 mL OF BLOOD FOR EACH IOHEXOL BLOOD DRAW IN THE PROVIDED SST.**
- **RECORDING THE EXACT NUMBER OF MINUTES ON THE TIMER IS MORE IMPORTANT THAN DRAWING THE BLOOD EXACTLY AT 120 & 300 MINUTES AFTER IOHEXOL INFUSION. FOR EXAMPLE, IF BLOOD IS DRAWN AT 133 MINS INSTEAD OF 120 MINS, DOCUMENT BLOOD DRAWN @ 133 MINS.**
- **TIME SHOULD BE RECORDED IMMEDIATELY AFTER EACH BLOOD SAMPLE IS OBTAINED (i.e., B1, B2).**

**POST VITALS SHOULD BE TAKEN 10 MINUTES AFTER INFUSION**
**USING LOCAL BLOOD PRESSURE MEASUREMENT (i.e. DINAMAP)**

- **If rash develops after Iohexol Infusion, consider it a reaction to Iohexol and notify PI immediately. Consider administration of 1 mg/kg Benadryl IV (maximum dose: 50 mg Benadryl IV).**
- **In the rare event that systolic BP decreases more than 25 mm Hg, diastolic BP decreases more than 20 mmHg, or pulse increases more than 20 beats per min, notify PI immediately to evaluate reaction and complete the Adverse Event (ADVR) Form. Consider the possibility of an anaphylactic reaction to Iohexol. Consider administration of 1 mg/kg Benadryl IV (maximum dose: 50 mg Benadryl IV). Draw up to 0.1 mL 1:1000 Epinephrine for SQ injection and 2 mg/kg Solumedrol IV for administration as ordered by physician.**

| **(i) Post Vitals:** | | |
|---|---|---|
| G2a. | Post- infusion blood pressure: | ___ ___ ___ / ___ ___ ___ |
| b. | Post-infusion temperature: | ___ ___ ___ . ___<br>1 = ºC Typical range: **36.1 – 38.3**<br>2 = ºF Typical range: **94.5 – 100.6** |
| c. | Post-infusion number of heart beats per minute: | ___ ___ ___ |
| d. | Post-infusion respirations per minute: | ___ ___ |

**INVERT TUBE 5-10 TIMES AFTER EACH BLOOD DRAW**
**LET SST TUBE STAND 30 MINUTES (BUT NO LONGER THAN 1 HOUR)**
**CENTRIFUGE AT MAX SPEED BETWEEN 1100-1300g (3000rpm with 10cm radius rotor) for 10 MINUTES IN SWING HEAD OR 15 MINUTES IN FIXED ANGLE (BALANCE TUBES IN CENTRIFUGE)**

| | ALL TIMES should be documented from the initial infusion time | (i) ACTUAL HOURS/ MINUTES on TIMER | (ii) **ONLY** if Timer malfunctions, record Clock Time using the same clock used for G1a | (iii) Difficult Blood Draw: Yes | No | (iv) Blood Drawn via Venipuncture Yes | No | (v) Blood Volume Collected (1 mL): | (vi) Centrifuged at Clinical Site: Yes | No |
|---|---|---|---|---|---|---|---|---|---|---|
| G3a. | **B1 2 hrs** (120 min): | ___ **hr** ___ ___ mins | __ __ : __ __ 1 = AM 2 = PM | 1 **(Skip to b)** | 2 | 1 | 2 | ___ . ___ mL | 1 **(Skip to G4a)** | 2 **(Skip to G4a)** |
| b. | **B1** 2nd attempt: | ___ **hr** ___ ___ mins | __ __ : __ __ 1 = AM 2 = PM | 1 | 2 | 1 | 2 | ___ . ___ mL | 1 | 2 |
| G4a. | **B2 5 hrs** (300 min): | ___ **hr** ___ ___ mins | __ __ : __ __ 1 = AM 2 = PM | 1 **(Skip to b)** | 2 | 1 | 2 | ___ . ___ mL | 1 **(Skip to H2)** | 2 **(Skip to H2)** |
| b. | **B2** 2nd attempt: | ___ **hr** ___ ___ mins | __ __ : __ __ 1 = AM 2 = PM | 1 | 2 | 1 | 2 | ___ . ___ mL | 1 | 2 |

## SECTION H:

H2. Were nail clippings and hair samples previously collected and shipped at V1b?
Yes..... 1 **(END)**
No..... 2

H3. Did the participant consent to have biological samples (i.e., nail clippings and hair samples) stored at NIDDK Biorepository?
Yes..... 1
No..... 2 **(END)**

# NAIL CLIPPING COLLECTION

- Collection of fingernails is preferred. **DO NOT** collect fingernail clippings if the participant has acrylic nails, or nail fungus or discoloration causing pain or discomfort. If the participant cannot provide fingernail clippings, the Study Coordinator may clip the participant's toenails instead. **FINGERNAILS AND TOENAILS SHOULD NOT BE COLLECTED IN THE SAME CRYOVIAL** (collect one or the other).

- STAINLESS STEEL NAIL CLIPPERS MUST BE USED TO COLLECT NAIL CLIPPINGS. Use small (pediatric size) stainless steel nail clippers (see Figure A) for younger participants and large stainless steel nail clippers (see Figure B) for older participants. Both sizes are included in the CKiD starter package.

- Clean the blades of the nail clippers with **SaniZide Plus** prior to use (provided by the CBL).
- Whenever possible, the Study Coordinator should clip all (10) fingernails, removing approximately 1 millimeter from each nail (See Figure C). **Be prepared to collect flyaway nails.**
- (To use nail clippers, see Figures A – D). Refer to CKiD MOP Section 12 for further details.
- Carefully place the nail clippings into the cryovial (see Figure D). After using the nail clipper, spray the clipper with **SaniZide Plus** and wipe with clean cloth.


**Figure A**

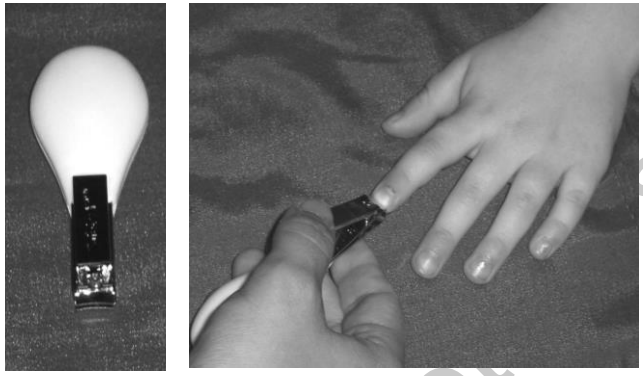


**Figure B**

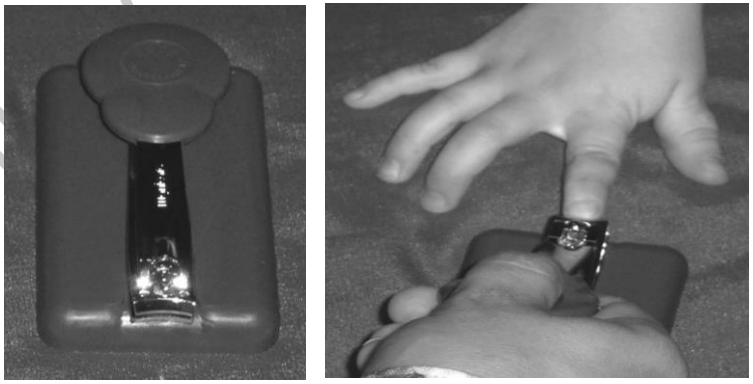
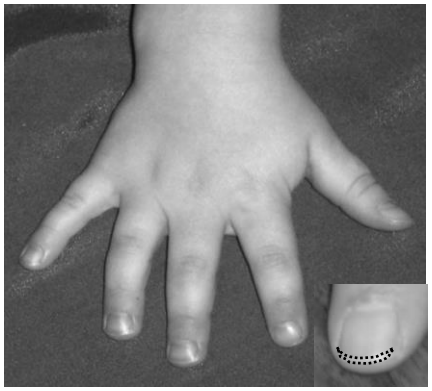


**Figure C**



Provide 10 nail clippings that are at least 1 mm tall

**Figure D**

H4. Does the participant have acrylic nails?

Yes..... 1 **(Skip to H6)**

No..... 2

H5. Were 10 fingernail clippings collected?

Yes..... 1 **(Skip to I1)**

No..... 2

a. How many fingernail clippings were collected?

___ ___

b. Specify reason "10" fingernail clippings were not collected.

Nails not long enough..... 1 **(Skip to H6)**

Participant Refused..... -7 **(Skip to H6)**

Other..... 2

i. Specify:_____

_____

H6. Were 10 toenail clippings collected?

Yes..... 1 **(Skip to I1)**

No..... 2

a. How many toenail clippings were collected?

___ ___

b. Specify reason "10" toenail clippings were not collected: (e.g., Nail fungus or discoloration causing pain or discomfort)

Nail fungus or discoloration..... 1 **(Skip to I1)**

Nails not long enough..... 2 **(Skip to I1)**

Participant Refused..... -7 **(Skip to I1)**

Other..... 3

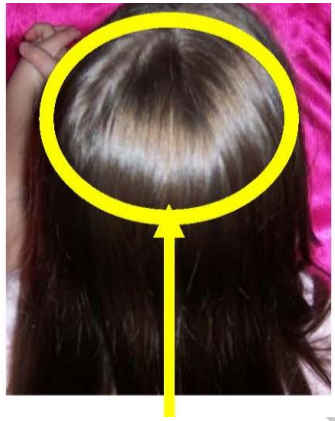
i. Specify:_____

_____

## SECTION I: HAIR SAMPLE COLLECTION

- STAINLESS STEEL SCISSORS MUST BE USED TO COLLECT HAIR SAMPLE. The scissors are included in the CKiD starter package.
- DO NOT collect hair sample if the participant has colored, or chemically altered hair
- Clean blades of stainless steel scissors with **SaniZide Plus** prior to use.
- Use powder-free gloves.
- Refer to CKiD MOP Section 12 for further details.
  - Lift up the top layer of hair from the **occipital** region of the scalp (see Figure A). Isolate a small thatch of hair (at least 20 fibers) from this region (see Figure B).
  - **Place the label with the participant's KID ID # tightly around all 20 strands of hair located at the distal end (furthest from the scalp)** (see Figure C).
  - Cut the hair sample off the participant's head **as close to the scalp as possible** (see Figure D).
  - Place cut thatch of hair inside aluminum foil (4 X 4) and fold the top of the foil to completely enclose the hair sample.
  - Place the aluminum foil inside a Ziplock bag (4 X 4) with the gel desiccant pellets in it and seal.
  - Store sample at room temperature in a dark place prior to shipment.
  - After using the scissors, spray scissors with **SaniZide Plus** and wipe with clean cloth**.**


**Figure A**



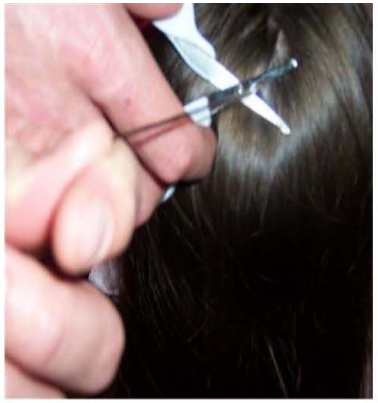
**Occipital Region of Scalp**

**Figure B**

**Figure C**

**Place the KID ID label tightly around all 20 strands.**

**Figure D**



**Cut the hair sample off the participant's head *as close to the scalp as possible.***

I1. Does the participant have permed, dyed, colored, or chemically altered hair?

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

No..... 2

I2. Was the Study Coordinator able to cut at least 20 fibers of hair from the **occipital** region?

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

No..... 2

a. Specify reason "20" hair fibers were not collected:

Hair not long enough..... 1 **(END)**

Participant Refused..... -7 **(END)**

Other..... 2

i. Specify:_____

_____

# SPECIMEN COLLECTION FORM for ODD Follow-up Visits (3, 5, 7…) (L31)

## CKiD Chronic Kidney Disease in Children Cohort Study
## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: ___ ____

A3. FORM VERSION: 0 3 / 0 1 / 1 8

A4. SPECIMEN COLLECTION DATE: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. FORM COMPLETED BY (INITIALS): ___ ___ ___

---

**The following sample should be collected.**

| Samples: | Shipped to: | Shipped: |
|---|---|---|
| **Serum** | **CBL** | **IMMEDIATELY** |
| **Serum** | **CBL** | **BATCHED (Ship in Jan, Apr, Jul or Oct)** |
| **Plasma** | **CBL** | **BATCHED (Ship in Jan, Apr, Jul or Oct)** |
| **Urine** | **CBL** | **IMMEDIATELY** |

**Please refer to questions 27 on the Eligibility Form to determine if biological consent was obtained.**

**Depending on the type of consent, the following samples may or may not be collected:**

| Samples: | Shipped to: | Shipped: |
|---|---|---|
| ***Serum (Biological)*** | ***NIDDK Biorepository*** | **BATCHED (Ship in Jan, Apr, Jul or Oct)** |
| ***Plasma (Biological)*** | ***NIDDK Biorepository*** | **BATCHED (Ship in Jan, Apr, Jul or Oct)** |
| ***Urine (Biological)*** | ***NIDDK Biorepository*** | **BATCHED (Ship in Jan, Apr, Jul or Oct)** |
| ****Whole Blood (Genetic)*** | ***NIDDK Biorepository*** | ***IMMEDIATELY*** |

***ONLY collect whole blood for NIDDK Biorepository, if sample was not collected at V1b OR if sample collected at V1b was inadequate.**

**BATCHED SAMPLES SHOULD BE SHIPPED QUARTERLY (Jan, Apr, July or Oct) OR MORE OFTEN IF DESIRED BY THE SITE COORDINATOR!**

**Samples should NOT be stored for more than one year.**
**For specific questions, contact your CCC prior to shipment.**

## SECTION B: PREGNANCY TEST AND FIRST MORNING URINE COLLECTION

B1. Is participant a female of child-bearing potential?

Yes..... 1 **(See PROMPT Below)**
No..... 2 **(Skip to B3)**

***PROMPT: QUESTION B2 IS FOR FEMALE PARTICIPANTS OF CHILD-BEARING POTENTIAL ONLY. URINE PREGNANCY TEST DATE MUST FALL WITHIN 72 HOURS BEFORE STUDY VISIT DATE.***

B2. a. Urine pregnancy test date: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

b. Urine pregnancy results:
Positive..... 1 **(END; COMPLETE TRANSITIONAL FORM)**
Negative..... 2

# FIRST MORNING URINE COLLECTION

Obtain urine collected at home in the specimen container that was shipped to the family before the visit.
IF URINE WAS NOT collected at home, collect FRESH urine sample during CKiD visit.

Pour at least 1 mL of urine into the CBL transport tube.

Check that all information is correct on the urine collection tube and follow packaging instructions and ship to CBL.

| **Reasons Code List*:** | | | |
|---|---|---|---|
| | 1= Not required | 4 = Collection Contamination | 7 = Insufficient Volume |
| | 2 = Difficult Urine Collection | 5 = Inadvertently Destroyed | |
| | 3 = Participant Refused | 6 = Oversight | |

| **Sample Type (Required Volume):** | **(a) Sample Obtained:** Yes | No | **(b) If No, specify reason** *SEE CODE LIST ABOVE | **(c) Additional Requirements:** |
|---|---|---|---|---|
| B3. Urine Creatinine, Urine Protein, Urine Albumin (CBL) (1 mL–10 mL) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to C1)** | i. Is this a first morning urine sample? Yes.....1 No.....2<br>ii. Time of Collection: __ __ : __ __ 1 = am, 2 = pm |

## SECTION C: Visit 3 BLOOD DRAW

**For Initial Blood Draw with Syringe, Vacutainer OR Butterfly Method: Select the Type of Consent Obtained (options 1 through 4):**

**ONLY collect whole blood for NIDDK Biorepository, if sample was not collected at V1b or sample collected at V1b was inadequate.**

### 1 If participant consented to both BIOLOGICAL AND GENETIC samples:

Collect **22.5-23.5** mL if participant is **< 30 kg** **OR** **28.5-29.5** mL if participant is **≥ 30 kg**.

If **< 30 kg**, immediately transfer **(using 18 gauge needle)** or draw:

- If not collected at V1b - 6 mL into (1) 6mL ACD tube for Genetic sample (**ACD Tube must be COMPLETELY FILLED**)
- 10 mL into (2) Tiger-Top SST for CBL and NIDDK Biorepository
- 4 mL into two (2) PSTs for CBL and NIDDK Biorepository
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 1.5 mL in appropriate tube *(not provided)* for local Renal Panel
- ***1 mL of additional blood in SST for CBL (if initial sample is grossly hemolyzed)***

If **≥ 30 kg**, immediately transfer **(using 18 gauge needle)** or draw:

- If not collected at V1b - 6 mL into (1) 6mL ACD tube for Genetic sample **(ACD Tube must be COMPLETELY FILLED)**
- 14 mL into (2) Tiger-Top SST for CBL and NIDDK Biorepository
- 6 mL into two (2) PSTs for NIDDK Biorepository
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 1.5 mL in appropriate tube *(not provided)* for local Renal Panel
- ***1 mL of additional blood in SST for CBL (if initial sample is grossly hemolyzed)***

### 2 If participant consented to BIOLOGICAL samples ONLY:

Collect **16.5-17.5** mL if participant is **< 30 kg** **OR** **22.5-23.5** mL if participant is **≥ 30 kg**.

If **< 30 kg**, immediately transfer **(using 18 gauge needle)** or draw:

- 10 mL into (2) Tiger-Top SSTs for CBL & NIDDK Biorepository
- 4 mL into one (1) PSTs for CBL and NIDDK Biorepository
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 1.5 mL in appropriate tube *(not provided)* for local Renal Panel
- ***1 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)***

If **≥ 30 kg**, immediately transfer **(using 18 gauge needle)** or draw:

- 14 mL into (2) Tiger-Top SSTs for CBL & NIDDK Biorepository
- 6 mL into (2) PST for NIDDK Biorepository
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 1.5 mL in appropriate tube *(not provided)* for local Renal Panel
- ***1 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)***

### 3 If participant consented to GENETIC samples ONLY, collect 13.5-14.5 mL from all participants (regardless of weight):

Immediately transfer or draw:

- If not collected at V1b - 6 mL into (1) 6mL ACD tube for Genetic sample (ACD Tube must be COMPLETELY FILLED)
- 4mL into (1) Tiger-Top SST for CBL
- 1 mL into PST for CBL
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 1.5 mL in appropriate tube *(not provided)* for local Renal Panel
- ***1 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)***

### 4 If participant did NOT consent to BIOLOGICAL samples and Genetic samples:

Collect **7.5-8.5** mL from all participants (regardless of weight) as specified below.

Immediately transfer (using 18 gauge needle) or draw:

- 4 mL into (1) Tiger-Top SSTs for CBL
- 1 mL into PST for CBL
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 1.5 mL in appropriate tube *(not provided)* for local Renal Panel
- ***1 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)***

# SECTION C: Visit 3 BLOOD DRAW PROCESSING

## CBL & NIDDK BR (Serum)

Invert the Tiger Top SST 5 times gently to mix.

Stand SST upright to allow clotting at room temperature for 30 mins and not more than 1 hour (60 mins).

Centrifuge SST at MAX SPEED between 1100-1300g (3000rpm with 10cm radius rotor) for 10 mins in swinghead OR 15 mins in fixed angle. *If incomplete separation, centrifuge again 10-15 mins.

You must send hemolyzed sample to CBL. Also if the sample is **GROSSLY HEMOLYZED (Dark Red),** then collect 1 mL of additional blood in a SST. Centrifuge and then transfer serum into the extra Orange Top Transport Tube provided.

**If sample is moderately, slightly or NOT HEMOLYZED, proceed with CBL and NIDDK BR preparation.**

**CBL Studies**
Using the disposable pipette, pipette 0.5 of serum into Orange Top Transport Tube labeled "Serum CBL" for CBL renal/uric acid). Follow packaging instructions and ship to CBL with accompanying forms and urine. **No FRIDAY shipments.** Refrigerate specimen and ship on next business day.

**NIDDK (Serum)**
Pipette 3mL (<30kg) or 5mL (≥30kg) serum into clear top cryovial for NIDDK BR (use different pipettes for serum and plasma).
**If there is any extra serum, then pipette the extra serum into the clear top cryovial marked "NIDDK BR SERUM"*

Store sample in freezer at -70ºC or lower, batch up to 40 samples and ship during **Jan, Apr, Jul and Oct**. When shipper is needed, complete "NIDDK BR Shipper Request Form" on CKiD website: http://www.statepi.jhsph.edu/ckid/admin Then, follow packaging instructions.

**iPTH/hsCRP**
Pipette 0.5 mL of serum into a red top cryovial tube for CBL iPTH &, hsCRP

**Vitamin D**
Pipette 0.5 mL of serum into a red top cryovial for CBL Vitamin D

**Cystatin C**
Using the disposable pipette, pipette 0.5 mL of serum into Blue Screw-Top Cryovial for Cystatin C.

Store sample in freezer at -70ºC or lower and batch up to 20 samples and ship quarterly during the months of **January, April, July and October**. When shipper is needed, complete "CBL Dry Ice Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ Then, follow packaging instructions and ship to CBL with accompanying forms. **No FRIDAY shipments.** Ship on next business day.

## CBL & NIDDK BR (Plasma)

Invert each PST 8-10 times gently to mix.

Centrifuge each PST at 1100-1300g for 10 mins (swinghead) **OR** 15 mins (fixed angle).

**FGF-23**
Pipette 0.5 mL of plasma into a cryovial with green cap insert for CBL FGF-23

Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) plasma into cryovial with green cap insert (use different pipettes for serum and plasma).
**If there is any extra plasma, then pipette the extra plasma into the green cap insert cryovial marked "PLASMA (Extra)".*

Store sample in freezer at -70ºC or lower, batch up to 40 samples and ship during the months of **Jan, April, July and Oct**. When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ Then, follow packaging instructions.

## NIDDK BR (Whole Blood for DNA)

Invert the ACD Tube 6 times gently to mix blood with additives.

Keep tube at room temperature. **DO NOT FREEZE.**

Follow packaging instructions, complete DNA Collection Form and ship immediately to NIDDK Biorepository with accompanying forms. **Specimen can be shipped on**

Complete "On-line Shipping Form" on CKiD website to notify KIDMAC that sample(s) have been shipped.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ to notify the appropriate personnel from the CBL and the NIDDK BR.

# SECTION C: Visit 3 BLOOD DRAW AND PROCESSING

C1. ACTUAL TIME OF BLOOD DRAW ____ ____ : ____ ____ 1 = AM 2 = PM

| **Reasons Code List*:** | 1= Not required | 4 = Red Blood Cell Contamination | 7 = Exceed maximum allowable volume |
|---|---|---|---|
| | 2 = Difficult Blood Draw | 5 = Inadvertently Destroyed | |
| | 3 = Participant Refused | 6 = Oversight | |

| **Sample Type (Required Volume in Top Color Tube Type):** | **(a) Sample Obtained:** Yes / No | **(b) If No, specify reason** *SEE CODE LIST ABOVE | **(c) Additional Requirements:** |
|---|---|---|---|
| C2a. Renal/Uric Acid Chemistries (1.0 mL in Tiger Top SST) | 1 **(skip to c→)** / 2 | ___ ___ **(skip to C2b)** | **Indicate the appearance of the serum after centrifuging.** Grossly (Dark Red).....1 Moderately (Red/Light Red).....2 Slightly (Pink)..... .....3 Not Hemolyzed (Yellow).....4 |
| C2b. Cystatin C (1.0 mL in Tiger Top SST) | 1 **(skip to c→)** / 2 | ___ ___ **(skip to C3)** | Date Frozen: ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y |
| C3a. Serum for iPTH, hsCRP & Vitamin D (2.0 mL of blood in Tiger Top SST) | 1 **(skip to c→)** / 2 | ___ ___ **(skip to C3b)** | Date Frozen: ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y |
| C3b. Plasma for FGF-23 (1.0 mL of blood in PST) | 1 **(skip to c→)** / 2 | ___ ___ **(skip to C4a)** | Date Frozen: ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y |
| C4a. Local CBC (1.0 mL in Lavender Top tube) | 1 **(skip to C4b)** / 2 | ___ ___ **(skip to C4b)** | **N/A** |
| C4b. Local Renal Panel (1.5 mL in Local SST) | 1 **(skip to C5)** / 2 | ___ ___ **(skip to C5)** | **N/A** |



Sites can obtain results for lab values that have been identified as “KEY VARIABLES”. To obtain results, go the CKiD Nephron Website: **https://statepiaps8.jhsph.edu/nephron/groups/aspproc/**, click on “Report Menu” and choose the appropriate lab report (i.e., Selected Renal Panel Lab Variables Report.)

C5. Did the participant consent to have biological samples (i.e., serum, plasma and urine) stored at NIDDK Biorepository?

Yes..... 1

No..... 2 **(Skip to E1)**

| | | | |
|---|---|---|---|
| **Reasons Code List*:** | 1= Not required | 4 = Red Blood Cell Contamination | 7 = Exceed maximum allowable volume |
| | 2 = Difficult Blood Draw | 5 = Inadvertently Destroyed | |
| | 3 = Participant Refused | 6 = Oversight | |

| **Sample Type (Required Volume in Top Color Tube Type):** | **(a) Sample Obtained:** Yes | No | **(b) If No, specify reason** ***SEE CODE LIST ABOVE** | **(c) Additional Requirements:** |
|---|---|---|---|---|
| C6. Serum for NIDDK Biorepository (**6.0 mL or **10.0 mL of blood in Tiger Top SST) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to C7)** | Date Frozen: ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y |
| C7. Plasma for NIDDK Biorepository (***3.0 mL of blood (1) Green Top or ***5.0 mL (2) Green Top PSTs) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to D1)** | Date Frozen: ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y |

** Collect 6.0 mL of whole blood for participants < 30 kg and 10.0 mL for participants ≥ 30 kg

*** Collect 3.0 mL of whole blood for participants < 30 kg and 5.0 mL for participants ≥ 30 kg

## SECTION D: Visit 3 URINE COLLECTION AND PROCESSING FOR REPOSITORY

Collect FRESH urine into an initial urine collection cup or hat (provided by the site).

Pour 15-60 mL (preferably 60 mL) of FRESH urine into 90 mL urine collection cup with 4 protease inhibitor tablets. Do not fill the urine past the 60 mL mark on the collection cup. One protease inhibitor tablet should be used for 10-15 mL of urine **(see Table A)**. For example if 30 mL of urine is collected, ONLY 2 PI tablets are needed. (Like all unused supplies, **unused protease inhibitor tablets should be returned to the CBL**.)

**TABLE A:**

| Urine Volume | # of Protease Inhibitor Tablets |
|---|---|
| 10 – 15 mL | **1** |
| 16 – 30 mL | **2** |
| 31 – 45 mL | **3** |
| 46 – 60 mL | **4** |

Invert the urine cup gently 5 – 10 times.

The PROTEASE INHIBITOR TABLET(s) MUST BE **COMPLETELY** DISSOLVED in the urine.

Once the protease inhibitor tablet(s) are completely dissolved, pour urine into up to six (6) 10 mL urine centrifuge tubes.
(**For each tube:** remove yellow top cap, pour urine into tube and SCREW cap back onto tube.) Place no more than 10 mL in each tube.
**-- OR –**
**Sites may also substitute with tubes normally used to centrifuge urine at site.**

Centrifuge urine tube(s) at MAX SPEED between 1100-1300g (3000rpm with 10cm radius rotor) for 10 mins (swinghead units) **– OR –** 15 mins (fixed angle units).

Decant (pour off) the supernates (liquid reaction) into up to seven (7) 10 mL urine cryovials. Pour no more than 9 mL of urine into each 10 mL cryovial to allow for expansion.

Check that all information is correct on the urine cryovials, promptly freeze and store sample(s) at -70ºC or lower. Batch samples and ship at least quarterly (include maximum of 36 cryovials per shipper). When shipper(s) is needed, complete *"NIDDK Shipper Request Form"* on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/. Then, follow packaging instructions.

When pickup has been scheduled, complete *"Online Shipping Form"* on CKiD website to notify the NIDDK BR and KIDMAC that sample(s) have been shipped to NIDDK BR.

**Reasons Code List*:** 1= Not required | 2 = Difficult Urine Collection | 3 = Participant Refused | 4 = Collection Contamination | 5 = Inadvertently Destroyed | 6 = Oversight | 7 = Insufficient volume

| Sample Type (Required Volume in Top Color Tube Type): | (a) Sample Obtained: Yes | (a) Sample Obtained: No | (b) If No, specify reason *SEE CODE LIST ABOVE | (c) Additional Requirements: |
|---|---|---|---|---|
| D1. Urine for NIDDK Biorepository (15.0 - 60.0 mL of urine in specimen container and transferred into collection cup with protease inhibitors) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to D2→)** | i. Was supernate decanted into urine transport cryovials? Yes.....1 No.....2<br>ii. Date Frozen: ___ ___ /___ ___ /___ ___ ___ ___ (M M D D Y Y Y Y) |

## OPTIONAL LOCAL LAB TEST (IF CLINICALLY INDICATED)

Check with the PI at your clinical site to determine whether or not it is **CLINICALLY INDICATED** to obtain urine for local lab. These are instances when the PI needs results immediately and/or the participant needs additional local labs performed (i.e., local Urine Creatinine and Urine Protein).

D2. Was a urine protein to creatinine ratio assay performed at the clinical site's local laboratory?

Yes..... 1 → **Complete Local Urine Assay Results Form L06, ONLY if local labs are CLINICALLY INDICATED**
No..... 2

## SECTION E: WHOLE BLOOD FOR NIDDK BIOREPOSITORY

**BLOOD FOR GENETIC TESTING AT THE NIDDK BIOREPOSITORY SHOULD BE SHIPPED ONLY IF THE SAMPLE WAS NOT COLLECTED AT V1B OR IF THE SAMPLE OBTAINED AT V1B WAS INADEQUATE (i.e, cell lines were not immortalized).**

**If participant has consented to have whole blood stored at NIDDK Biorepository but it is not necessary to collect the whole blood, Code question E2b as "01."**

E1. Did the participant consent to have whole blood stored at NIDDK Biorepository?
Yes..... 1
No..... 2 **(END FORM)**

| **Reasons Code List*:** | | | |
|---|---|---|---|
| | 1= Not required | 3 = Participant Refused | 5 = Inadvertently Destroyed |
| | 2 = Difficult Blood Draw | 4 = Red Blood Cell Contamination | 6 = Oversight |

| **Sample Type (Required Volume in Top Color Tube Type):** | **(a) Sample Obtained:** Yes | No | **(b) If No, specify reason** ***SEE CODE LIST ABOVE** | **(c) Additional Requirements:** |
|---|---|---|---|---|
| E2. Whole Blood for NIDDK Biorepository (6 mL of blood in 1 (6 mL) ACD tube) | 1 **(skip to c→)** | 2 | ___ ___ **(END FORM)** | i. Date of Blood Draw: ___ ___ /___ ___ /___ ___ ___ ___ M M D D Y Y Y Y<br>ii. Blood Drawn By : ____ ____ (initials)<br>iii. Gender of participant : Male.....1 Female.....2<br>iv. Age of participant : ____ ____ years |

## SPECIMEN COLLECTION FORM for EVEN Follow-up Visits 4, 6, 8, … (L41)

### CKiD Chronic Kidney Disease in Children Cohort Study

### SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: ___ ____

A3. FORM VERSION: 0 3 / 0 1 / 1 8

A4. SPECIMEN COLLECTION DATE: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. FORM COMPLETED BY (INITIALS): ___ ___ ___

---

**The following samples should be collected.**

| **Samples:** | **Shipped to** | **Shipped:** |
|---|---|---|
| **Serum** | **CBL** | **IMMEDIATELY** |
| **Serum** | **CBL** | **Batched (Ship in Jan, Apr, Jul or Oct)** |
| **Urine** | **CBL** | **IMMEDIATELY** |
| **Iohexol Blood*** | **CBL** | **IMMEDIATELY** |

*** COLLECT IOHEXOL BLOOD DRAW: Only if Cohort 3 participants who consent to iohexol protocol or Cohorts 1 & 2 participants had previous iGFR>90**

**If consent is obtained for biological samples, collect the following:**

| **Samples:** | **Shipped to:** | **Shipped:** |
|---|---|---|
| **Serum (Biological)** | **NIDDK Biorepository** | **Batched (Ship in Jan, Apr, Jul or Oct)** |
| **Plasma (Biological)** | **NIDDK Biorepository** | **Batched (Ship in Jan, Apr, Jul or Oct)** |
| **Urine (Biological)** | **NIDDK Biorepository** | **Batched (Ship in Jan, Apr, Jul or Oct)** |
| **Toenail Clippings (Biological)** | **NIDDK Biorepository** | **IMMEDIATELY** |

**BATCHED SAMPLES SHOULD BE SHIPPED QUARTERLY (Jan, Apr, July or Oct) OR MORE OFTEN IF DESIRED BY THE SITE COORDINATOR!**

**Samples should NOT be stored for more than one year.**
**For specific questions, contact your CCC prior to shipment.**

## SECTION B: PREGNANCY TEST AND FIRST MORNING URINE COLLECTION

B1. Is participant a female of child-bearing potential?

Yes..... 1 **(See PROMPT Below)**
No..... 2 **(Skip to B3)**

***PROMPT: QUESTION B2 IS FOR FEMALE PARTICIPANTS OF CHILD-BEARING POTENTIAL ONLY. URINE PREGNANCY TEST DATE MUST FALL WITHIN 72 HOURS BEFORE STUDY VISIT DATE.***

***If performing iohexol protocol, B2 MUST BE COMPLETED BEFORE IOHEXOL TESTING IS INITIATED.***

B2. a. Urine pregnancy test date: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

b. Urine pregnancy results:

Positive..... 1 **(END; COMPLETE TRANSITIONAL FORM)**

Negative..... 2

# FIRST MORNING URINE COLLECTION

Obtain urine collected at home in the specimen container that was shipped to the family before the visit.
IF URINE WAS NOT collected at home, collect FRESH urine sample during CKiD visit.

(Refer to MOP Section 11 and/or CBL flowchart for additional information and directions)

Pour at least1mL of urine into the CBL transport tube.

↓

Check that all information is correct on the urine collection tube and follow packaging instructions and ship to CBL.

| **Reasons Code List*:** | 1= Not required | 3 = Participant Refused | 5 = Inadvertently Destroyed | 7=Insufficient Volume |
|---|---|---|---|---|
| | 2 = Difficult Urine Collection | 4 = Collection Contamination | 6 = Oversight | |

| **Sample Type (Required Volume):** | **(a) Sample Obtained:** Yes | No | **(b) If No, specify reason** ***SEE CODE LIST ABOVE** | **(c) Additional Requirements:** |
|---|---|---|---|---|
| B3. Urine Creatinine, Urine Protein, Urine Albumin (CBL) (1 mL–10 mL) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to C1)** | i. Is this a first morning urine sample? Yes.....1 No.....2 |
| | | | | ii. Time of Collection: __ __ : __ __ 1 = am, 2 = pm |

# SPECIMEN COLLECTION FORM for EVEN Follow-up Visits 4, 6, 8, … (L41)

## SECTION C: Visit 4 BLOOD DRAW

**For Initial Blood Draw with Syringe, Vacutainer OR Butterfly Method:**
**Select the Type of Consent Obtained (options 1 through 3) That Pertains to the CKiD Participant:**

**1** **If participant consented to BIOLOGICAL samples:**
Collect **14-15** mL if participant is < **30 kg** **OR** **20-21** mL if participant is ≥ **30 kg**.

If < **30 kg**, immediately transfer **(using 18 gauge needle)** or draw:
- 8.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK Biorepository
- 3 mL into (1) PST for NIDDK Biorepository
- 1 mL in lavender-top tube for local CBC *(tube not provided in CBL kit)*
- 1.5 mL in appropriate tube *(not provided)* for local Renal Panel
- ***1 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)***

If ≥ **30 kg**, immediately transfer **(using 18 gauge needle)** or draw:
- 12.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK Biorepository
- 5 mL into (2) PST for NIDDK Biorepository
- 1 mL in lavender-top tube for local CBC *(tube not provided in CBL kit)*
- 1.5 mL in appropriate tube *(not provided)* for local Renal Panel
- ***1 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)***

**2** **If participant did NOT consent to BIOLOGICAL samples:**
Collect **5-6** mL from all participants (regardless of weight) as specified below.

Immediately transfer (using 18 gauge needle) or draw:
- 2.5 mL into (1) Tiger-Top SSTs for CBL
- 1 mL in lavender-top tube for local CBC *(tube not provided in CBL kit)*
- 1.5 mL in appropriate tube *(not provided)* for local Renal Panel
- ***1 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)***

**3** **For Participant Completing Iohexol Study Visit**
Only Cohort 3 participants who consent to iohexol protocol or Cohorts 1 & 2 participants with previous iGFR>90

For IOHEXOL study visits:
- ***1mL of additional blood into Tiger Top SST for CBL Iohexol Blank (B0) blood sample***

Iohexol is infused at the time of initial blood draw.
Refer to page 10 for **Instructions for Iohexol Infusion and GFR Blood Draws.**

# PROCESSING OF BLOOD FOR CBL & NIDDK BR

Invert the SST 5 times & PST 8-10 times gently to mix.

Stand SST upright to allow clotting at room temperature for 30 mins and not more than 1 hour (60 mins).

Centrifuge SST & PST at MAX SPEED between 1100-1300 g (3000rpm with 10cm radius rotor) for 10 minutes in swinghead units **OR** 15 minutes in fixed angle units (balance tube in centrifuge).*If incomplete separation, centrifuge again for 10-15 minutes.

**If sample is GROSSLY HEMOLYZED.**

You must send hemolyzed sample to CBL. If participant has eaten, aliquot hemolyzed sample for fasting lipid profile and send to CBL. Also, if the sample is **GROSSLY HEMOLYZED (Dark Red),** collect 1 mL of additional blood in a SST**.** Centrifuge and then transfer serum into the extra Orange Top Transport Tube provided.

**If sample is moderately, slightly or NOT HEMOLYZED, proceed with CBL and NIDDK BR preparation.**

**For IOHEXOL STUDY VISITS ONLY:**
**B0 sample**

Using the disposable pipette, pipette 0.5 mL of serum into Round-bottom Orange Top Transport Tube labeled "B0" for Iohexol Blank (B0) sample. Follow packaging instructions and ship to CBL with accompanying forms, iohexol blood draws and urine. **No FRIDAY shipments.** Refrigerate specimen and ship on next business day.

**CBL Studies**

Using the disposable pipette, pipette 0.75 mL of serum into Orange Top Transport Tube labeled "Serum CBL" for CBL renal/uric acid and lipid. Follow packaging instructions and ship to CBL with accompanying forms, iohexol blood draws, and urine. **No FRIDAY shipments.** Refrigerate specimen and ship on next business day.

**Cystatin C**

Using the disposable pipette, pipette 0.5 mL of serum into Blue Screw-Top Cryovial for Cystatin C. Store sample in freezer at -70°C or lower, batch up to 20 samples and ship on dry ice every four months to the CBL. When shipper is needed, complete "CBL Dry Ice Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ Then, follow packaging instructions and ship to CBL with accompanying forms. **No FRIDAY shipments.** Ship on next business day.

**NIDDK BR (Serum & Plasma)**

Pipette 3 mL (<30kg) or 5 mL (≥ 30kg) of serum into clear top cryovial & 1.5 (<30kg) or 2.5 mL(≥ 30kg) of plasma into cryovial into green cap insert (use different pipettes for serum and plasma). **If there is any extra serum and/or plasma, then pipette the extra serum into the clear top cryovial marked "NIDDK BR SERUM" and the extra plasma in green cap insert cryovial marked "PLASMA (Extra)."* Store samples in freezer at -70°C or lower, & batch up to 40 samples and ship on dry ice in January, April, July or October to the NIDDK BR. When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/. Then, follow packaging instructions.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ to notify the appropriate personnel from the CBL and the NIDDK BR.

# SPECIMEN COLLECTION FORM for EVEN Follow-up Visits 4, 6, 8, … (L41)

C1. ACTUAL TIME OF BLOOD DRAW ____ ____ : ____ ____ 1 = AM 2 = PM

***PROMPT: IF SUSPECTED BLOOD DRAW ADVERSE EVENT (i.e., infection), complete ADVERSE EVENT (ADVR) Form***

**Reasons Code List*:**
1= Not required
2 = Difficult Blood Draw
3 = Participant Refused
4 = Red Blood Cell Contamination
5 = Inadvertently Destroyed
6 = Oversight
7 = Exceed maximum allowable volume

| **Sample Type (Required Volume in Top Color Tube Type):** | **(a) Sample Obtained:** Yes / No | **(b) If No, specify reason** *SEE CODE LIST ABOVE | **(c) Additional Requirements:** |
|---|---|---|---|
| C2. Renal/Uric Acid Chemistries (2.0 mL in Tiger Top SST) | 1 **(skip to c→)** / 2 | ___ **(skip to C3)** | **Indicate the appearance of the serum after centrifuging.**<br>Grossly (Dark Red).....1<br>Moderately (Red/Light Red).....2<br>Slightly (Pink)..... .....3<br>Not Hemolyzed (Yellow).....4 |
| C3. Cystatin C (1.0 mL in Tiger Top SST) | 1 **(skip to c→)** / 2 | ___ ___ **(skip to C4a)** | Date Frozen:<br>___ ___ / ___ ___ /___ ___ ___ ___<br>M M D D Y Y Y Y |
| C4a. Local CBC (1.0 mL in Lavender Top tube) | 1 **(skip to C4b)** / 2 | ___ ___ **(skip to C4b)** | **N/A** |
| C4b. Local Renal Panel (1.5 mL in Local SST) | 1 **(skip to C5)** / 2 | ___ ___ **(skip to C5)** | **N/A** |
| C5. Serum for Fasting Lipid Panel (0.5 mL in Tiger Top SST) | 1 **(skip to c→)** / 2 | ___ ___ **(skip to C6)** | **Did the participant fast after midnight?**<br>Yes…….....1<br>No…….....2* |

*If the participant did not fast, the Nephron Lipid Report will indicate that the participant did not fast.

Sites can obtain results for lab values that have been identified as “KEY VARIABLES”. To obtain results, go the CKiD Nephron Website: **https://statepiaps8.jhsph.edu/nephron/groups/aspproc/**, click on “Report Menu” and choose the appropriate lab report (i.e., Selected Renal Panel Lab Variables Report.)

C6. Did the participant consent to have biological samples (i.e., serum, plasma and urine samples) stored at the NIDDK Biorepository?

Yes..... 1

No..... 2 **(Skip to E2)**

| **Reasons Code List*:** | 1= Not required | 4 = Red Blood Cell Contamination | 7 = Exceed maximum allowable volume |
|---|---|---|---|
| | 2 = Difficult Blood Draw | 5 = Inadvertently Destroyed | |
| | 3 = Participant Refused | 6 = Oversight | |

| **Sample Type (Required Volume in Top Color Tube Type):** | **(a) Sample Obtained:** Yes | No | **(b) If No, specify reason** ***SEE CODE LIST ABOVE** | **(c) Additional Requirements:** |
|---|---|---|---|---|
| C7. Serum for NIDDK Biorepository (**6.0 mL or **10.0 mL of blood in Tiger Top SST) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to C8)** | Date Frozen: ___ ___/___ ___/___ ___ ___ ___ M M D D Y Y Y Y |
| C8. Plasma for NIDDK Biorepository (***3.0 mL of blood in one Green Top or ***5.0 mL in two Green Top PSTs) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to D1)** | Date Frozen: ___ ___/___ ___/___ ___ ___ ___ M M D D Y Y Y Y |

** Collect 6.0 mL of whole blood for participants < 30 kg and 10.0 mL for participants ≥ 30 kg

*** Collect 3.0 mL of whole blood for participants < 30 kg and 5.0 mL for participants ≥ 30 kg

# SPECIMEN COLLECTION FORM for EVEN Follow-up Visits 4, 6, 8, … (L41)

## SECTION D: URINE COLLECTION AND PROCESSING FOR REPOSITORY

Collect FRESH urine into an initial urine collection cup or hat (provided by the site).

Pour 15-60 mL (preferably 60 mL) of FRESH urine into 90 mL urine collection cup with 4 protease inhibitor tablets. Do not fill the urine past the 60 mL mark on the collection cup. One protease inhibitor tablet should be used for 10-15 mL of urine **(see Table A)**. For example if 30 mL of urine is collected, ONLY 2 PI tablets are needed. (Like all unused supplies, **unused protease inhibitor tablets should be returned to the CBL**.)

**TABLE A:**

| Urine Volume | # of Protease Inhibitor Tablets |
|---|---|
| 10 – 15 mL | **1** |
| 16 – 30 mL | **2** |
| 31 – 45 mL | **3** |
| 46 – 60 mL | **4** |

Invert the urine cup gently 5 – 10 times.

The PROTEASE INHIBITOR TABLET(s) MUST BE **COMPLETELY** DISSOLVED in the urine.

Once the protease inhibitor tablet(s) are completely dissolved, pour urine into up to six (6) 10 mL urine centrifuge tubes.
(**For each tube:** remove yellow top cap, pour urine into tube and SCREW cap back onto tube.) Place no more than 10 mL in each tube.
**-- OR –**
**Sites may also substitute with tubes normally used to centrifuge urine at site.**

Centrifuge urine tube(s) at MAX SPEED between 1100-1300g (3000rpm with 10cm radius rotor) for 10 mins (swinghead units) **– OR –** 15 mins (fixed angle units).

Decant (pour off) the supernates (liquid reaction) into up to seven (7) 10 mL urine cryovials. Pour no more than 9 mL of urine into each 10 mL cryovial to allow for expansion.

Check that all information is correct on the urine cryovials, promptly freeze and store sample(s) at -70ºC or lower. Batch samples and ship at least quarterly (include maximum of 36 cryovials per shipper). When shipper(s) is needed, complete *"NIDDK Shipper Request Form"* on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/. Then, follow packaging instructions.

When pickup has been scheduled, complete *"Online Shipping Form"* on CKiD website to notify the NIDDK BR and KIDMAC that sample(s) have been shipped to NIDDK BR.

**Reasons Code List*:** 1= Not required | 2 = Difficult Urine Collection | 3 = Participant Refused | 4 = Collection Contamination | 5 = Inadvertently Destroyed | 6 = Oversight | 7 = Insufficient volume

| Sample Type (Required Volume in Top Color Tube Type): | (a) Sample Obtained: Yes | (a) Sample Obtained: No | (b) If No, specify reason *SEE CODE LIST ABOVE | (c) Additional Requirements: |
|---|---|---|---|---|
| D1. Urine for NIDDK Biorepository (15.0 - 60.0 mL of urine in specimen container and transferred into collection cup with protease inhibitors) | 1 **(skip to c→)** | 2 | ___ ___ **(skip to E2)** | i. Was supernate decanted into urine transport cryovials? Yes.....1 No.....2<br>ii. Date Frozen: ___ ___ /___ ___ /___ ___ ___ ___ M M D D Y Y Y Y |

## SECTION E: OPTIONAL TESTS

## LOCAL LAB TEST (IF CLINICALLY INDICATED)

Check with the PI at your clinical site to determine whether or not it is **CLINICALLY INDICATED** to obtain urine for local lab. These are instances when the PI needs results immediately and/or the participant needs additional local labs performed (i.e., local Urine Creatinine and Urine Protein).

E2. Was a urine protein to creatinine ratio assay performed at the clinical site's local laboratory?

Yes..... 1 → **Complete Local Urine Assay Results Form L06, ONLY if local labs are CLINICALLY INDICATED**
No..... 2

## IOHEXOL PROTOCOL

E3. Is the participant completing iohexol study visit?
Yes, consent obtained..... 1
No..... 2 → **(Skip to Section H)**

## ONLY COMPLETE SECTIONS F & G IF PARTICIPANT IS COMPLETING IOHEXOL STUDY VISIT.

**Only Cohort 3 participants who consent to iohexol protocol or Cohorts 1 & 2 participants with previous iGFR>90 should complete iohexol protocol. If you have additional questions, contact CCC.**
**For an iohexol study visit, additional blood (including blood for the Iohexol "B0" Blank sample) should be collected for Iohexol-Based GFR.**

## SECTION F: INFUSION SYRINGE WEIGHT

F1. **SCALE MUST FIRST BE ZEROED BEFORE WEIGHING. REMOVE ALUMINUM FOIL PRIOR TO WEIGHING THE SYRINGE. THE SAME SCALE MUST BE USED TO WEIGH THE SYRINGE PRE AND POST IOHEXOL INFUSION.**

a. Syringe Weight **Pre-Iohexol Infusion**: ___ ___ . ___ ___ (g)

b. Syringe Weight **Post-Iohexol Infusion**: ___ ___ . ___ ___ (g) (Post-Infusion Weight should be **at least 6.0g** less than Pre-Infusion Weight. If Post-Infusion Weight is not at least 6g less, please confirm.)

**PRE AND POST SYRINGE WEIGHT MUST BE OBTAINED IN ORDER TO CALCULATE PARTICIPANT'S GFR.**

## SECTION G: IOHEXOL – Refer to Instructions for Iohexol Infusion and GFR Blood Draws Flow Chart on Page 10

- **BEFORE** INFUSING **5 mL OF** IOHEXOL, **SET TIMER = 0**. SIMULTANEOUSLY START TIMER AND BEGIN IOHEXOL INFUSION
- **COMPLETE INFUSION BETWEEN 1 TO 2 MINS**
- LEAVE TIMER RUNNING THROUGHOUT IOHEXOL INFUSION AND SUBSEQUENT BLOOD DRAWS

## Instructions for Iohexol Infusion and GFR Blood Draws for Make-up GFRs

Place two IV lines (18-22 gauge polyethylene catheters) using two separate vascular access sites
---OR---
Place one butterfly and one IV line (18-22 gauge polyethylene catheter) using two separate vascular access sites; use tape to stabilize butterfly for iohexol infusion
--OR---
Use butterfly for pre-iohexol and individual blood draw sticks; use tape to stabilize butterfly for Iohexol infusion

↓

Complete pre-iohexol infusion blood draw according to instructions

↓

Start timer and infuse iohexol over 1-2 minutes
**If infusion site for iohexol IV or butterfly infiltrates, study MUST BE DISCONTINUED**
**Must wait at least 48 hours to repeat study, and repeat visit should occur within 3 months of initial**

↓

Flush with 10 mL normal saline to ensure infusion of all of the iohexol; **IOHEXOL IV OR BUTTERFLY MAY NOW BE REMOVED**

↓

**10 minutes post-infusion**
**CHECK POST-INFUSION VITALS**
**DO NOT DRAW BLOOD AT 10 MINUTES**

→ If rash develops, consider it a reaction to iohexol and **notify PI immediately**. Consider administering 1mg/kg Benadryl IV (maximum dose 50mg).

If systolic BP decreases > 25 mm Hg, diastolic BP decreases > 20 mm Hg or pulse increases > 20 beats per min, consider this an anaphylactic reaction to iohexol and **notify PI immediately**; consider administering 1 mg/kg Benadryl IV (maximum dose 50 mg) and draw up to 0.1 mL 1:1000 Epinephrine for SQ injection and 2 mg/kg Solumedrol IV if necessary.

↓

COMPLETE ADVERSE EVENT FORM and send to CCC for data entry

↓

Obtain post-infusion weight of syringe on the same scale as prior to infusion. Record weight on the Specimen Collection Form prior to shipment to the CCC

↓

Draw 1 ml of blood into SST at 120 mins (B1), and 300 mins (B2).

*For IV ONLY: Discard initial 1 mL blood waste at each blood draw (or per device guidelines)

*For IV ONLY: Flush after each blood draw with at least 3 mL normal saline

*Record the time each blood draw is completed

→ If blood draw is difficult with poor volume delivery, repeat draw 5 minutes later; record time on Specimen Collection Form and tube. If blood draw is impossible, repeat with new venipuncture.

↓

Following each blood draw: gently invert tube 5-10 times → Stand SST upright at room temp for 30 minutes, but no longer than 1 hour → Centrifuge at MAX SPEED between 1100-1300 g for 10 minutes in swinghead or 15 minutes in fixed angle*

↓

Transfer serum into the cryovial labeled "Iohexol Serum."

↓

Following packaging and shipping instructions; send urine, blood and copies of completed shipping form(s) & confirmation of written consent to CBL

**Physician should be immediately available (in person or by phone) during Iohexol Infusion**
**Encourage fluids throughout the visit.**
*1100-1300 g = 3000 rpm with 10 cm radius rotor

G1. IOHEXOL INFUSION

a. INFUSION START TIME: ____ ____ : ____ ____ 1 = AM 2 = PM

- **DO NOT DRAW BLOOD FROM THE IV SITE WHERE IOHEXOL WAS INFUSED. ANOTHER IV SITE MUST BE USED.**
- **WASTE 1 mL OF BLOOD IF DRAWING FROM A SALINE/HEPARIN LOCK (OR PER DEVICE GUIDELINES).**
- **COLLECT 1 mL OF BLOOD FOR EACH IOHEXOL BLOOD DRAW IN THE PROVIDED SST.**
- **RECORDING THE EXACT NUMBER OF MINUTES ON THE TIMER IS MORE IMPORTANT THAN DRAWING THE BLOOD EXACTLY AT 120 & 300 MINUTES AFTER IOHEXOL INFUSION. FOR EXAMPLE, IF BLOOD IS DRAWN AT 133 MINS INSTEAD OF 120 MINS, DOCUMENT BLOOD DRAWN @ 133 MINS.**
- **TIME SHOULD BE RECORDED IMMEDIATELY AFTER EACH BLOOD SAMPLE IS OBTAINED (i.e., B1, B2).**

**POST VITALS SHOULD BE TAKEN 10 MINUTES AFTER INFUSION**
**USING LOCAL BLOOD PRESSURE MEASUREMENT (i.e. DINAMAP)**

- **If rash develops after Iohexol Infusion, consider it a reaction to Iohexol and notify PI immediately. Consider administration of 1 mg/kg Benadryl IV (maximum dose: 50 mg Benadryl IV).**
- **In the rare event that systolic BP decreases more than 25 mm Hg, diastolic BP decreases more than 20 mmHg, or pulse increases more than 20 beats per min, notify PI immediately to evaluate reaction and complete the Adverse Event (ADVR) Form. Consider the possibility of an anaphylactic reaction to Iohexol. Consider administration of 1 mg/kg Benadryl IV (maximum dose: 50 mg Benadryl IV). Draw up to 0.1 mL 1:1000 Epinephrine for SQ injection and 2 mg/kg Solumedrol IV for administration as ordered by physician.**

| **(i) Post Vitals:** | | |
|---|---|---|
| G2a. | Post- infusion blood pressure: | ___ ___ ___ / ___ ___ ___ |
| b. | Post-infusion temperature: | ___ ___ ___ . ___<br>1 = ºC Typical range: **36.1 – 38.3**<br>2 = ºF Typical range: **94.5 – 100.6** |
| c. | Post-infusion number of heart beats per minute: | ___ ___ ___ |
| d. | Post-infusion respirations per minute: | ___ ___ |

**INVERT TUBE 5-10 TIMES AFTER EACH BLOOD DRAW**
**LET SST TUBE STAND 30 MINUTES (BUT NO LONGER THAN 1 HOUR)**
**CENTRIFUGE AT MAX SPEED BETWEEN 1100-1300g (3000rpm with 10cm radius rotor) for 10 MINUTES IN SWING HEAD OR 15 MINUTES IN FIXED ANGLE (BALANCE TUBES IN CENTRIFUGE)**

| | **ALL TIMES should be documented from the initial infusion time** | **(i) ACTUAL HOURS/ MINUTES on TIMER** | (ii) **ONLY** if Timer malfunctions, record Clock Time using the same clock used for G1a | **(iii) Difficult Blood Draw:** Yes | No | **(iv) Blood Drawn via Venipuncture** Yes | No | **(v) Blood Volume Collected (1 mL):** | **(vi) Centrifuged at Clinical Site:** Yes | No |
|---|---|---|---|---|---|---|---|---|---|---|
| G3a. | **B1 2 hrs** (120 min): | ___ **hr** ___ ___ mins | __ __ : __ __ 1 = AM 2 = PM | 1 **(Skip to b)** | 2 | 1 | 2 | ___ . ___ mL | 1 **(Skip to G4a)** | 2 **(Skip to G4a)** |
| b. | **B1** 2nd attempt: | ___ **hr** ___ ___ mins | __ __ : __ __ 1 = AM 2 = PM | 1 | 2 | 1 | 2 | ___ . ___ mL | 1 | 2 |
| G4a. | **B2 5 hrs** (300 min): | ___ **hr** ___ ___ mins | __ __ : __ __ 1 = AM 2 = PM | 1 **(Skip to b)** | 2 | 1 | 2 | ___ . ___ mL | 1 **(Skip to H1a)** | 2 **(Skip to H1a)** |
| b. | **B2** 2nd attempt: | ___ **hr** ___ ___ mins | __ __ : __ __ 1 = AM 2 = PM | 1 | 2 | 1 | 2 | ___ . ___ mL | 1 | 2 |

**TOENAIL CLIPPINGS FOR THE REPOSITORY SHOULD BE SHIPPED ONLY IF THE SAMPLE WAS NOT COLLECTED AT V4**

## SECTION H:

H1 a. Is this a study Visit 4? Yes..... 1 **(skip to H1c)**
No..... 2

b. Were toenail clippings collected at Visit 4? Yes..... 1 **(END; if toenail clippings collected at V4 do not collect at V6)**
No..... 2

c. Did the participant consent to have biological samples (i.e., nail clippings) stored at NIDDK Biorepository?
Yes..... 1
No..... 2 **(END)**

# TOENAIL CLIPPING COLLECTION

- **The collection of TOENAILS is preferred. DO NOT** collect fingernail clippings. Also DO NOT collect toenails if participant has nail fungus, or discoloration causing pain or discomfort.

- STAINLESS STEEL NAIL CLIPPERS MUST BE USED TO COLLECT NAIL CLIPPINGS. Use small (pediatric size) stainless steel nail clippers (see Figure A) for younger participants and large stainless steel nail clippers (see Figure B) for older children. Both sizes are included in the CKiD starter package.

- Clean the blades of the nail clippers with **SaniZide Plus** prior to use (provided by the CBL).
- Whenever possible, the Study Coordinator should clip all (10) toenails, removing approximately 1 millimeter from each nail (See Figure C). **Be prepared to collect flyaway nails.**
- (To use nail clippers, see Figures A – D). Refer to CKiD MOP Section 12 for further details.
- Carefully place the nail clippings into the cryovial (see Figure D). After using the nail clipper,
- spray the clipper with **SaniZide Plus** and wipe with clean cloth.


**ALTHOUGH PICTURES DEPICT THE CLIPPING OF FINGERNAILS, AT VISIT 4 TOENAIL CLIPPINGS ARE PREFERRED.**

**Figure A**

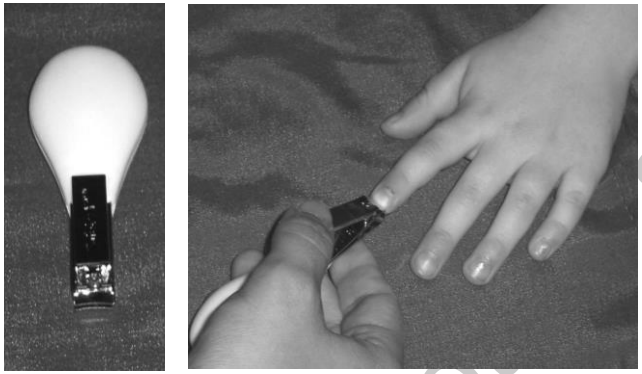


**Figure B**

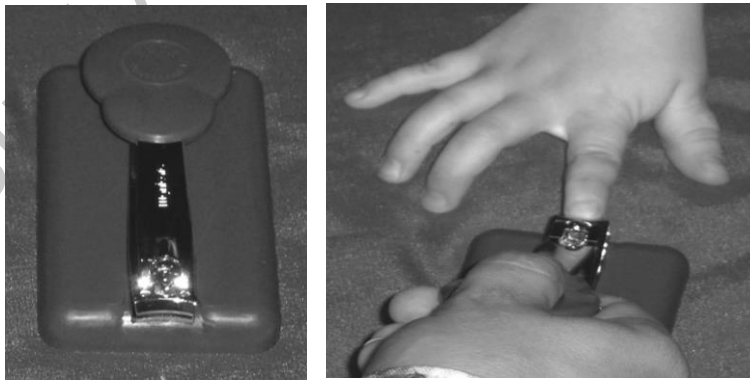
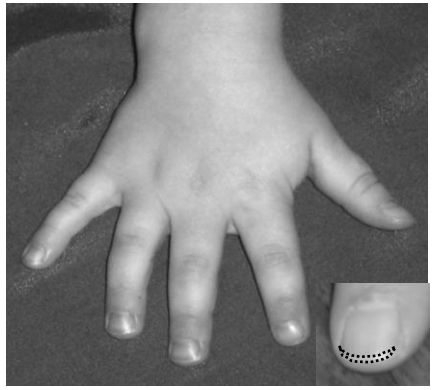


**Figure C**



Provide 10 nail clippings that are at least 1 mm tall

**Figure D**

H2. Were 10 toenail clippings collected?

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

No..... 2

a. How many toenail clippings were collected?

___ ___

b. Specify reason "10" toenail clippings were not collected: (e.g., Nail fungus or discoloration causing pain or discomfort)

Nail fungus or discoloration..... 1 **(END)**

Nails not long enough..... 2 **(END)**

Participant Refused..... -7 **(END)**

Other..... 3

i. Specify: _____

_____

**LOCAL LABORATORY – RENAL PANEL RESULTS**
**FORM L03**

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. Protocol type:
Regular Study Visit…….…… 0
Post-Dialysis Visit…….…… 1
Post-Transplant Visit…….. 2

A3. CKiD VISIT #: ___ ___

A4. FORM VERSION: 0 4 / 0 1 / 1 8

A5. DATE FORM COMPLETED: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A6. FORM COMPLETED BY (INITIALS):
___ ___

A7. Is this study visit an irregular (accelerated) visit?
Yes…… 1
No…… 2

**ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.**

### SECTION B

B1. ARE TEST RESULTS AVAILABLE?
Yes…… 1 **(B2)**
No, Sample Inadequate…… 2 **(END)**
No, Other Reason…… 3

_____
**(SPECIFY)**

B2. DATE SAMPLE DRAWN:

___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

B3. **Renal Panel Blood Results:**

| | | | |
|---|---|---|---|
| a. | Sodium | \|___\|___\|___\| | (MEQ/L) or (mmol/L) |
| b. | Potassium | \|___\| . \|___\| | (MEQ/L) or (mmol/L) |
| c. | Chloride | \|___\|___\|___\| | (MEQ/L) or (mmol/L) |
| d. | Carbon Dioxide | \|___\|___\| | (MEQ/L) or (mmol/L) |
| e. | Urea Nitrogen (BUN) | \|___\|___\|___\| | (mg/dL) |
| f. | Serum Creatinine | \|___\| . \|___\| | (mg/dL) |
| g. | Glucose (GLU) | \|___\|___\|___\| | (mg/dL) |
| h. | Calcium (CA) | \|___\|___\| . \|___\| | (mg/dL) |
| i. | Phosphate | \|___\|___\| . \|___\| | (mg/dL) |
| j. | Albumin | \|___\| . \|___\| | (g/dL) |

**LOCAL LABORATORY – CBC RESULTS**
**FORM L04**

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. Protocol type:

Regular Study Visit..... 0
Post-Dialysis Visit..... 1
Post-Transplant Visit..... 2

A3. CKiD VISIT #: ____ ____

A4. FORM VERSION: 0 4 / 0 1 / 1 8

A5. DATE FORM COMPLETED: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A6. FORM COMPLETED BY (INITIALS):

___ ___ ___

A7. Is this study visit an irregular (accelerated) visit?

Yes..... 1
No..... 2

**ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.**

## SECTION B

B1. ARE TEST RESULTS AVAILABLE?

Yes..... 1 **(B2)**
No, Sample Inadequate..... 2 **(END)**
No, Other Reason..... 3

_____
**(SPECIFY)**

B2. DATE SAMPLE DRAWN:

___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

## B3. CBC Blood Results:

a. Leukocyte Count (white blood cells) |___|___|___|___|___|* (cu mm)

| *Use the table below if results are reported in units of $10^3$uL. | |
|---|---|
| 4.5 x $10^3$ uL = 4500 cu mm | 9.0 x $10^3$ uL = 9000 cu mm |
| 5.0 x $10^3$ uL = 5000 cu mm | 9.5 x $10^3$ uL = 9500 cu mm |
| 5.5 x $10^3$ uL = 5500 cu mm | 10.0 x $10^3$ uL = 10000 cu mm |
| 6.0 x $10^3$ uL = 6000 cu mm | 10.5 x $10^3$ uL = 10500 cu mm |
| 6.5 x $10^3$ uL = 6500 cu mm | 11.0 x $10^3$ uL = 11000 cu mm |
| 7.0 x $10^3$ uL = 7000 cu mm | 11.5 x $10^3$ uL = 11500 cu mm |
| 7.5 x $10^3$ uL = 7500 cu mm | 12.0 x $10^3$ uL = 12000 cu mm |
| 8.0 x $10^3$ uL = 8000 cu mm | 12.5 x $10^3$ uL = 12500 cu mm |
| 8.5 x $10^3$ uL = 8500 cu mm | 13.0 x $10^3$ uL = 13000 cu mm |

b. Erythrocyte Count (red blood cells) |___| . |___|___| (M/cu mm) or (x$10^6$uL)

c. Platelet Count (PLTs) |___|___|___| (K/cu mm) or (x$10^3$uL)

d. Hemoglobin |___|___| . |___| (g/dL)

e. Packed Cell Volume (Hematocrit) |___|___| . |___| (%)

f. Mean Corpuscular Hemoglobin (MCH) |___|___| . |___| (pg/cell)

g. Mean Corpuscular Hemoglobin Concentration (MCHC) |___|___| . |___| (g/dL)

h. Mean Corpuscular Volume (MCV) |___|___|___|. |___| (fL)

i. Red Blood Cell Distribution Width (RDW) |___|___| . |___| (%)

**LOCAL LABORATORY – URINE ASSAY RESULTS**
**Form L06**
**(ONLY COMPLETE IF LOCAL URINE ASSAY WAS PERFORMED)**

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. Protocol type:
Regular Study Visit..... 0
Post-Transplant Visit..... 2

A3. CKiD VISIT #: ___ ___

A4. FORM VERSION: 0 4 / 0 1 / 1 8

A5. DATE FORM COMPLETED: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A6. FORM COMPLETED BY (INITIALS): ___ ___ ___

A7. Is this study visit an irregular (accelerated) visit? Yes..... 1
No..... 2

**ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.**

### SECTION B

B1. ARE TEST RESULTS AVAILABLE?

Yes..... 1 **(B2)**
No, Sample Inadequate..... 2 **(END)**
No, Other Reason..... 3

_____
**(SPECIFY)**

B2. DATE SAMPLE DRAWN: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

B3. **Components of Local Urine Protein Creatinine Ratio:**

a. Protein: |___||___|___|.|___| (mg/dl)

b. Creatinine: |___||___|___|.|___| (mg/dl)

## CENTRAL LABORATORY – RENAL PANEL TESTS

## FORM L05

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. Protocol type:

Regular Study Visit…….. 0
Post-Dialysis Visit…….. 1
Post-Transplant Visit…….. 2

A3. CKiD VISIT #: ____ ____

A4. FORM VERSION: 0 4 / 0 1 / 1 8

**ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.**

### SECTION B

B1. ARE TEST RESULTS AVAILABLE?

Yes .....1 **(B2)**
No, Sample Inadequate .....2 **(END)**
No, Other Reason.....3

_____ **(END)**
**(SPECIFY)**

B2. DATE SAMPLE DRAWN:

___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

## CENTRAL LABORATORY – RENAL PANEL TESTS

## FORM L05

B3. **Renal Panel Blood Results**

| | | | |
|---|---|---|---|
| a. | Sodium (NA) | \|___\|___\|___\| | (mmol/L) |
| b. | Potassium (K) | \|___\| . \|___\| | (mmol/L) |
| c. | Chloride (CL) | \|___\|___\|___\| | (mmol/L) |
| d. | Carbon Dioxide ($CO_2$) | \|___\|___\| | (mmol/L) |
| e. | Urea Nitrogen (BUN) | \|___\|___\|___\| | (mg/dL) |
| f. | Serum Creatinine – Enzmatic | \|___\| . \|___\| \|___\| | (mg/dL) |
| g. | Glucose (GLU) | \|___\|___\|___\| | (mg/dL) |
| h. | Calcium (CA) | \|___\|___\| . \|___\| | (mg/dL) |
| i. | Phosphate ($PO_4$) | \|___\|___\| . \|___\| | (mg/dL) |
| j. | Uric Acid (Urate) | \|___\| . \|___\| | (mg/dL) |
| k. | Albumin (ALB) | \|___\| . \|___\| | (g/dL) |

B4. a. Indicate the appearance of the serum |___|

Gross hemolysis..... 1
Moderate hemolysis..... 2
Slight hemolysis..... 3
No hemolysis..... 4

B5. Did participant complete post-dialysis visit?

Yes..... 1 **(END)**
No..... 2

B6. **Urine Results**

| | | | |
|---|---|---|---|
| a. | Creatinine, Urine | \|___\|___\|___\| | (mg/dL) |
| b. | Protein, Urine | \|___\|___\| | (mg/dL) |

**Enter "-1" for post-transplant visit participants**

| | | | |
|---|---|---|---|
| c. | Microalbumin | \|___\|___\| . \|___\| \|___\| | (mg/dL) |

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. Protocol type: Regular Study Visit…….. 0
Post-Transplant Visit…….. 2

A3. CKiD VISIT #: ___ ___

A4. FORM VERSION: **0 4 / 0 1 / 1 8**

**ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.**

### SECTION B

B1. ARE TEST RESULTS AVAILABLE?

Yes .....1 **(B2)**
No, Sample Inadequate .....2 **(END)**
No, Other Reason.....3

_____ **(END)**
**(SPECIFY)**

B2. DATE SAMPLE DRAWN:

___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

B2a. WHICH LABORATORY ANALYZED THE SAMPLE?

CBL…… 1

Minnesota…… 2

B3. IS THIS A 2-POINT CONCENTRATION?

Yes…….. 1

No…….. 2

B4. IS THIS A CALIBRATED CONCENTRATION?

Yes..... 1

No..... 2

| | **SECTION C:** | **IOHEXOL CONCENTRATIONS (mg/dL)** |
|---|---|---|
| C3. | **B** 120 min: | ___ ___ . ___ ___ |
| C3a | **B** 240 min: | ___ ___ . ___ ___ |
| C4. | **B** 300 min: | ___ ___ . ___ ___ |

**CENTRAL LABORATORY**
**Intact Parathyroid Hormone (iPTH) and High Sensitivity C-Reactive Protein (hsCRP)**
**FORM L08**

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. Protocol type:

Regular Study Visit..... 0
Post-Dialysis Visit..... 1
Post-Transplant Visit..... 2

A3. CKiD VISIT #: ____ ____

A4. FORM VERSION: 0 4 / 0 1 / 1 8

**ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.**

### SECTION B

B1. ARE TEST RESULTS AVAILABLE?

Yes .....1 **(B2)**
No, Sample Inadequate .....2 **(END)**
No, Other Reason.....3

_____ **(END)**
**(SPECIFY)**

B2. DATE SAMPLE DRAWN: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

B3. **iPTH & hsCRP Results:**

a. (intact) Parathyroid (iPTH) |___||___||___| . |___| (pg/mL)

b. High Sensitivity C-Reactive Protein (hs CRP) |___||___| . |___| |___| (mg/L)

c. Was serum sample shipped at room temperature? |___|

Yes.....1
No.....0

**CENTRAL LABORATORY – LIPID PROFILE**
**FORM L09**

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. Protocol type:
Regular Study Visit…….. 0
Post-Dialysis Visit…….. 1
Post-Transplant Visit…….. 2

A3. CKiD VISIT #: ____ ____

A4. FORM VERSION: 0 4 / 0 1 / 1 8

**ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.**

**SECTION B**

B1. ARE TEST RESULTS AVAILABLE?

Yes .....1 **(B2)**
No, Sample Inadequate .....2 **(END)**
No, Other Reason.....3

_____ **(END)**
**(SPECIFY)**

B2. DATE SAMPLE DRAWN: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

B3. **Lipid Profile Results:**

a. Cholesterol (CHOL) |___|___|___| (mg/dL)

b. Total Triglycerides (TRG) |___|___|___| (mg/dL)

c. High Density Lipoproteins (HDL) |___|___| (mg/dL)

d. Low Density Lipoproteins (LDL) |___|___|___| (estimated) (mg/dL)

e. CHOL/HDL Ratio |___| . |___|

## CENTRAL LABORATORY – CYSTATIN C RESULTS

## FORM L11

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. Protocol type:

Regular Study Visit…….. 0
Post-Transplant Visit…….. 2

A3. CKiD VISIT #: ____ ____

A4. FORM VERSION: 0 4 / 0 1 / 1 8

**ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.**

### SECTION B

B1. ARE TEST RESULTS AVAILABLE?

Yes .....1 **(B2)**
No, Sample Inadequate .....2 **(END)**
No, Other Reason.....3

_____ **(END)**
**(SPECIFY)**

B2. DATE SAMPLE DRAWN: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

B3. Which laboratory analyzed the sample?

CBL…… 1

B4. Was IFCC standard used?

Yes, IFCC standard used.....1
No, IFCC standard was not used.....2

B5. Serum Cystatin C – CBL |___| |___| . |___| |___| (mg/L)

## CENTRAL LABORATORY – IRON TESTS

## FORM L12

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: ____ ____

A3. FORM VERSION: 0 7 / 0 1 / 0 8

**ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.**

### SECTION B

B1. ARE TEST RESULTS AVAILABLE?

Yes ..... 1 **(B2)**
No, Sample Inadequate..... 2 **(END)**
No, Other Reason ..... 3

_____ **(END)**
**(SPECIFY)**

B2. DATE SAMPLE DRAWN:

___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

## CENTRAL LABORATORY – IRON TESTS

## FORM L12

B3. **Iron Results**

| | | | |
|---|---|---|---|
| a. | Serum Iron | \|___\|___\|___\| | (ug/dL) |
| b. | Total Iron-Binding Capacity (TIBC) | \|___\|___\|___\| | (ug/dL) |
| c. | Tranferrin Saturation (TSAT) | \|___\|___\| | (%) |
| d. | Ferritin | \|___\|___\|___\| | (ng/dL) |
| e. | Transferrin | \|___\|___\|___\| | (mg/dL) |

## CENTRAL LABORATORY – VITAMIN D

## FORM L13

## Chronic Kidney Disease in Children (CKiD)

## SECTION A: GENERAL INFORMATION

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

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: ____ ____

A3. FORM VERSION: 1 0 / 1 5 / 0 9

**ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.**

### SECTION B

B1. ARE TEST RESULTS AVAILABLE?

Yes .....1 **(B2)**
No, Sample Inadequate .....2 **(END)**
No, Other Reason.....3

_____ **(END)**
**(SPECIFY)**

B2. DATE SAMPLE DRAWN:

___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

## CENTRAL LABORATORY – VITAMIN D

## FORM L13

B3. **Vitamin D 25 Hydroxy Results**

a. 25-OH Vitamin D2 |___|___|___| (ng/mL)

b. 25-OH Vitamin D3 |___|___|___| (ng/mL)

c. 25-OH Vitamin Total |___|___|___| (ng/mL)