BASELINE GENERAL AND MEDICAL HISTORY (BS)

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

A3. FORM VERSION: 0 1 / 0 1 / 2 5

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

A5. SITE COORDINATOR'S INITIALS: ___ ___ ___

A6. Protocol type:
Regular Study Visit..... 0
Post-Dialysis Visit..... 1 **(Skip to A7)**
Post-Transplant Visit..... 2 **(Skip to A7)**

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

INTRODUCTION TO PARTICIPANT/PARENT OR OTHER ADULT:

Thank you for participating in this study. In this survey, please note that the terms "you" and "your" refers to the CKiD participant.

The following pages contain questions about your family background, birth history, developmental history, family medical history and health 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 your background. If you have trouble understanding anything, please feel free to ask your clinical site coordinator for further clarification.

SECTION C: PARTICIPANT'S BACKGROUND

The following questions are about your background.

B1. What is your date of birth?

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

Chronic Kidney Disease in Children

B2. What is your assigned gender at birth?

Male..... 1
Female..... 2

B3. Were you born in the United States of America (USA)?

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

a. Were you born in Canada?

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

b. In what country were you born?

_____

c. When did you move to the U.S. or Canada?

___ ___ ___ ___ (Year)

Don't Know..... -8

B4. a. Are you 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 B5)**
Don't Know..... -8 **(Skip to B5)**

b. Which language do you speak most frequently?

English..... 1
Spanish..... 2
Both (participant is bilingual)..... 3

B5. Which of the following describes your race? **(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 B6)**

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

CKiD Chronic Kidney Disease in Children

B6. Which hand do you primarily use to write?

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

SECTION C: PARTICIPANT'S BIRTH

The next questions are about your birth. Remember, the terms "you" and "your" refers to the CKiD participant. You may need to consult with your parents to answer these questions. The following questions also ask about your biological parents. Biological parents are defined as the participant's birth or blood-related father or mother.

C1. Was your birth weight in pounds (lbs) or kilograms (kg)?

lbs..... 1
kg..... 2 **(Skip to b)**
Don't Know..... -8 **(Skip to C2)**

a. What was your birth weight in lbs and ounces?

___ ___ lbs ___ ___ oz **(Skip to C2)**

b. What was your birth weight in kilograms?

___ . ___ kg

C2. What was your 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

C3. Were you born in a hospital?

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

C4. How were you delivered?

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

C5. Were you born BEFORE the due date?

Yes..... 1
No..... 2 **(Skip to C6)**
Don't Know..... -8 **(Skip to C6)**

Chronic Kidney Disease in Children

a. How many weeks BEFORE the due date were you born?

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

Don't Know..... -8

b. Were you considered "pre-mature" at the time of your birth?

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

C6. Immediately after birth, did you spend time in the intensive care unit (ICU or NICU) before being allowed to go home?

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

C7. Immediately after birth, did you have any kidney problems?

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

C8. How long were you in the hospital after the delivery?

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

C9. What was the age of your biological mother when you were born?

___ ___ years

Don't Know..... -8

C10. Is your 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

C11. Which of the following describes the race of your 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 C12)**

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

C12. What is the **current** height of your birth mother?

___ feet ___ ___ inches

Don't Know..... -8

C13. What is the **current** weight of your birth mother?

___ ___ ___ lbs

Don't Know..... -8

C14. What was the age of your biological father when you were born?

___ ___ years

Don't Know..... -8

C15. Is your 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

C16. Which of the following describes the race of your 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 D1)**

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

CKiD Chronic Kidney Disease in Children

C17. What is the **current** height of your birth father?

___ feet ___ ___ inches

Don't Know..... -8

C18. What is the **current** weight of your birth father?

___ ___ ___ lbs

Don't Know..... -8

SECTION D: PARTICIPANT'S DEVELOPMENTAL HISTORY

The following questions are to learn more about your development. Please consult with your parents to complete these questions. Also, 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.

D1. At what age did you first perform the following activities?

		Age		Don't Know	Not yet achieved
a.	Walk alone.....	___ ___	months	-8	99
b.	Understand first words.....	___ ___	months	-8	99
c.	Speak first words.....	___ ___	months	-8	99

Please answer the next question based on whether a doctor or health care professional has told your parents/legal guardians that you had any of the following problems.

D2. When you were under 4 years old, did you 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

The next questions ask breast-feeding, bottle-feeding and toilet training.

D3. a. Were you breast-fed?

Yes..... 1

No..... 2 → **(Skip to D4)**

Don't Know..... -8 → **(Skip to D4)**

Chronic Kidney Disease in Children

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

A3. FORM VERSION: 0 1 / 0 1 / 2 5

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, and young adults 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 and young adults 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, such as Swisher Sweets, Middleton's, Black & Mild, or Backwoods)?

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, Starbuzz, JUUL, Vuse, Elf Bar, or Eso Bars. 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. In the past year, how many times have you used methamphetamines (also called speed, crystal meth, crank, ice, or meth)?

___ ___ ___ times

D8. 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. Protocol type:

Regular Study Visit..... 0
Post-Dialysis Visit..... 1
Post-Transplant Visit..... 2

A3. CKiD VISIT #: ___ ___

A4. FORM VERSION: 0 1 / 0 1 / 2 5

A5. DATE OF VISIT:

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

A6. INTERVIEWER'S INITIALS: ___ ___ ___

This form is to be completed by children, 12 years old or older, and young adults 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 and young adults 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.

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

B1. In the past year, have you smoked tobacco (e.g., a whole cigarette, cigar, cigarillo or little cigar such as Swisher Sweets, Middleton's, Black & Mild, or Backwoods)?

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, Starbuzz, JUUL, Vuse, Elf Bar, or Eso Bars. 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, how many times have you used methamphetamines (also called speed, crystal meth, crank, ice, or meth)?

___ ___ ___ times

D8. 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.

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 1 / 0 1 / 2 5

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

A5. SITE COORDINATOR'S INITIALS: ___ ___ ___

A6. Protocol type:
Regular Study Visit…….…. 0
Post-Dialysis Visit…….…... 1 **(Skip to A8)**
Post-Transplant Visit……. 2 **(Skip to A8)**

A7. Is this study visit an irregular (accelerated) visit?
Yes…… 1
No…….... 2

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

INTRODUCTION TO PARTICIPANT/PARENT OR OTHER ADULT:

Thank you for participating in this study. In this survey, please note that the terms "you" and "your" refer to the CKiD participant.

The following pages contain questions about your family background and family medical history since your 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 that the information that is collected 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.

SECTION B: PARTICIPANT'S EDUCATION

The following questions are about your education. Specifically, the next question asks about the highest grade or level of school you have completed. For example, if you are currently in the 12th grade, then enter "11", if you are a sophomore in college, then enter "13"or you are currently in the 6th grade, then enter "5". In addition, if you completed high school or GED enter "12 years", if you completed 4-year college degree enter "16 years", and if you completed a 4-year doctoral degree enter "20 years."

B1. What is the **highest** grade or level of school that you have COMPLETED?

___ ___Grade

Don't Know……..…… -8
Not Applicable/child less than 5 years old
and does not attend pre-school/pre-k……... -1

B2. Do you attend school outside of the home?

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

B3. During the past school year, approximately how many days have you missed from school because of not feeling well?

___ ___ ___Days

Don't Know..... -8

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

B4. Do you 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 C1)**

B5. Do you 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 C: PARTICIPANT'S FAMILY AND PRIMARY HOUSEHOLD

The following questions are to learn more about your home and with whom you live. Remember, the terms "you" and "your" refer to the CKiD participant.

C1a. What is the current relationship between your **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

C1b. What is your current relationship status?

Single..... 1
Married..... 2
Non-Married partner..... 3

C2. Who do you identify as your primary support system? **(Check "Yes", "No" or "Don't Know" for EACH of the following)**

		Yes	No	Don't Know
a.	Parent/legal guardian/caregiver.....	1	2	-8
b.	Spouse/Partner.....	1	2	-8
c.	Other family member(s).....	1	2	-8
d.	Friend.....	1	2	-8
e.	Colleague/Co-worker.....	1	2	-8

The following questions ask about your household.

C3. How many people live in the household at least half the time?

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

C4. What is your current living status/arrangement? **(Select "Yes", "No" or "Don't Know" for EACH of the following.)**

		Yes	No	Don't Know
a.	Live Alone.....	1	2	-8
b.	Live with at least one parent/legal guardian....	1	2	-8
c.	Live with other family member.....	1	2	-8
d.	Live with spouse/significant other/partner.....	1	2	-8
e.	Live with roommate.....	1	2	-8

C5. Do any of the people, adults or children, living in the household at least half the time routinely smoke cigarettes, cigars, cigarillos or little cigars?

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

C6. What is the highest grade or level of school that your MOTHER (including birth, adoptive, stepmother, or Parent 1) has COMPLETED? For example, if completed high school enter "12 years", if completed 4-year college degree enter "16 years", and if completed a 4-year doctoral degree enter "20 years."

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

C7. What is the highest grade or level of school that your FATHER (including birth, adoptive, stepfather or Parent 2) has COMPLETED? For example, if completed high school enter "12 years", if completed 4-year college degree enter "16 years", and if completed a 4-year doctoral degree enter "20 years."

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

C8. 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 your 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**

C9a. What is the current employment status of your MOTHER (including birth, adoptive or stepmother)?

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 C9b**
Unemployed not seeking work	4	→ **Skip to C9b**
Student	5	→ **Skip to C9b**
Retired	6	→ **Skip to C9b**
Disability	7	→ **Skip to C9b**
No such person in household/Not Applicable	-1	→ **Skip to C9b**
Don't Know	-8	→ **Skip to C9b**

C9b. What is the current employment status of your FATHER (including birth, adoptive or stepfather)?

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 C9c**
Unemployed not seeking work	4	→ **Skip to C9c**
Student	5	→ **Skip to C9c**
Retired	6	→ **Skip to C9c**
Disability	7	→ **Skip to C9c**
No such person in household/Not Applicable	-1	→ **Skip to C9c**
Don't Know	-8	→ **Skip to C9c**

C9c. What is your current employment status?

	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 **(skip to C10)**	2	-1 **(skip to C10)**	-8 **(skip to C10)**
Currently enrolled student.....	1 **(skip to C10)**	2	-1 **(skip to C10)**	-8 **(skip to C10)**
Unemployed but seeking work.....	1 **(skip to C10)**	2	-1 **(skip to C10)**	-8 **(skip to C10)**
Unemployed not seeking work.....	1 **(skip to C10)**	2	-1 **(skip to B10)**	-8 **(skip to C10)**

C10. What is the zip code where you currently live at least half of the time?

___ ___ ___ ___ ___ ___

Don't Know..... -8

C11. Approximately, how many years have you lived at the current zip code?

___ ___ . ___ years

Don't Know..... -8

SECTION D: PARTICIPANT'S FAMILY HISTORY

The following questions ask about the medical history of your biological family. **Remember, the terms "you" and "your" refers to the CKiD participant.** Your biological family includes your birth mother, birth father, grandparents, aunts, uncles, full siblings, and first cousins. (This does not include great aunts, great uncles and great grandparents.) *Full siblings are defined as siblings with the same birth mother and birth father as you.*

Some people who lost their parents at an early age, or who were adopted, may not have information about their birth family. **If you are uncertain of the answer to any specific question, please select "Don't Know."**

D1. Do you have knowledge of the health history of any members of your birth family (i.e. parents, grandparents, aunts, uncles, siblings, and cousins)?

Yes..... 1
No..... 2 → **(Skip to Section E)**

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

D2. a. In the past year, have any of **your living or deceased biological family members** been told by a healthcare professional that they had kidney disease?

Yes..... 1
No..... 2 → **(Skip to D3)**
Don't know..... -8 → **(Skip to D3)**

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	**(C3)**	1	2	3	4	5 **(specify)** Specify: _____	-8

Next, the following questions ask about your biological family members.

D3. In the past year, have any of your **living or deceased** biological family members been told by a health care professional (any doctor, nurse, physician assistant, or nurse practitioner) that they had…

Medical Condition	No	Don't Know	Yes	If yes, who? Mother	Father	Sibling	Grandparent(s)	Aunt/Uncle(s)	Cousin(s)
a. Same kidney disease as you	2	-8	1	1	2	3	4	5	6
b. High Blood pressure or hypertension	2	-8	1	1	2	3	4	5	6
c. High Cholesterol	2	-8	1	1	2	3	4	5	6
d. Diabetes	2	-8	1	1	2	3	4	5	6
e. Stroke before the age of 50	2	-8	1	1	2	3	4	5	6
f. Heart Attack before the age of 50	2	-8	1	1	2	3	4	5	6
g. Dialysis as treatment for kidney disease	2	-8	1	1	2	3	4	5	6
h. Kidney transplant as treatment for kidney disease	2	-8	1	1	2	3	4	5	6

SECTION E: PARTICIPANT'S DISCHARGE CONTROL

E1. In the past year, have you had any wetness or leakage of urine (accidents) during the day or night?

Yes..... 1
No..... 2 → **(END FORM)**
Don't Know..... -8 → **(END FORM)**

a. In the past year, have you catheterized the bladder (i.e., put a tube in the bladder)?

Yes..... 1
No..... 2 → **(END FORM)**
Don't Know..... -8 → **(END FORM)**

i. In the past year, have you catheterized through the urethra?

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

ii. In the past year, have you been catheterized through a stoma?

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

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 1 / 0 1 / 2 5

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

A5. SITE COORDINATOR'S INITIALS: ___ ___ ___

A6. Protocol type:
Regular Study Visit…….. 0
Post-Dialysis Visit…….. 1 **(Skip to A8)**
Post-Transplant Visit…… 2 **(Skip to A8)**

A7. Is this study visit an irregular (accelerated) visit?
Yes…… 1
No…… 2

A8. INDICATE PERSON COMPLETING THE FORM
Participant (Child/young adult)..... 1
Parent or other adult..... 2
Both (Parent and Participant)..... 3

INTRODUCTION TO PARTICIPANT/PARENT OR OTHER ADULT:

In this survey, please note that the terms "you" and "your" refer to the CKiD participant. The following questions are about your health history, including information about the current and past diseases that you may have had in life. Dates may be hard to remember. Please take as much time as you need, so that the information that is collected 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 your clinical care. The first set of questions asks about your kidney disease. Whenever the term "health care provider" is used, it means any doctor, nurse, physician assistant or nurse practitioner you have ever seen.

SECTION B

B1. In the past year, have you been seen by a Urologist (adult or pediatric)?

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

B2. In the past year, have you had surgery to treat your kidney problems?

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

B3. In the past year, has a healthcare provider diagnosed you with a kidney infection with a fever?

Yes..... 1
No..... 2 **(Skip to B4)**
Don't Know..... -8 **(Skip to B4)**

a. In the past year, how many times did you have a kidney infection with a fever?

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

B4. Were you assigned female at birth?

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

B5. In the past year, have you started your menses (i.e. period)?

Yes..... 1
No..... 2 **(Skip to B6)**
Don't Know..... -8 **(Skip to B6)**

a. How old were you when you started your first period?

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

Thinking back over the past **seven (7) days**, use the scale provided to rate each of the following symptoms that were felt.

Item	Never	Rarely	Sometimes	Often	Always
B6. How often did you feel fatigue was beyond your control?	1	2	3	4	5
B7. How often were you too tired to think clearly?	1	2	3	4	5
B8. I have energy	1	2	3	4	5

Thinking back over the past ***seven (7) days including today***, use the number (0-10) to best reflect a description of your feelings.

B9. How would you describe your overall Quality of Life?

1 2 3 4 5 6 7 8 9 10

As bad as it can be — As good as it can be

SECTION C: GENERAL MEDICAL HISTORY

The next set of questions asks about diseases/illnesses that you have been treated for or developed in the past year. Remember, the term "you" refers to the CKiD participant.

In the past year, has a doctor or any other healthcare professional told you that you had or have developed any of the following diseases/illnesses?

(Please select "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, Rheumatoid 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 (skip to C4b)	-8 (skip to C4b)
1. How many different times did you have a UTI during this past year? ___ ___ times			
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. Stomach 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 (impacted stool causing leakage)	1	2	-8

C6. In the past year, has a doctor or healthcare professional told you that you have hypertension (high blood pressure) or that you should take medicine to lower blood pressure?

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

a. What is the status of your high blood pressure (i.e., hypertension)?

Taking medicine but BP still high (Continued problem) 1
No longer has high blood pressure (Resolved problem) 2
Taking medicine and BP no longer high (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 you have hepatitis?

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

C8. In the past year, has a doctor or healthcare professional told you that you have any other infection(s)?

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

Please indicate whether you had or have developed any of the following problems in the past year.

(Please select "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.	Skin Cancer	1	2	-8
d.	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:_____

Please indicate whether you have or have had any of the following problems.
(Please select "Yes", "No" or "Don't Know" for EACH of the following.)

		Yes	No	Don't Know
C11.	NEUROLOGICAL			
a.	Seizures/Convulsions	1	2	-8
b.	Grinds Teeth	1	2	-8
c.	No control of Bowel Movements	1	2	-8
C12.	HEARING			
a.	Ear Infections	1	2	-8
C13.	VISION			
a.	Vision Problems (that can not be corrected with glasses/contacts)	1	2	-8
b.	Wears Glasses/Contacts	1	2	-8

SECTION D: ORTHOPEDIC HISTORY

The next set of questions asks about any orthopedic injuries you may currently have or that you 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 you had any broken bones?	1	2 **(Skip to D2)**	-8 **(Skip to D2)**

a. Please indicate which of the following bones were broken.
(Please select "Yes", "No" or "Don't Know" for EACH of the following.)

		Yes	No	Don't Know
1.	Arm/Elbow.....	1	2	-8
2.	Wrist/Hand.....	1	2	-8
3.	Knee/Leg.....	1	2	-8
4.	Ankle/Foot.....	1	2	-8
	Other	1	2	-8

D2. Do you have any bone disease in the hips?

Yes..... 1
No..... 2 **(Skip to E1)**
Don't Know..... -8 **(Skip to E1)**

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

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

SECTION E: HEALTHCARE UTILIZATION

These questions ask about all the places where you may have received care in the past year.

E1. In the past year, where have you gone to receive medical care?

(Please select "Yes" or "No" for EACH of the following places.)

Did you go to…

		Yes	No
a.	A clinic or health care center (not a part of a hospital)	1	2
b.	A private doctor's office (not a part of a clinic or hospital)	1	2
c.	Hospital Outpatient Department	1	2
d.	Urgent care	1	2
e.	The emergency room	1	2 **(Skip to f)**
	1. How many times have you received care at the emergency room in the past year? ___ ___		
f.	Some other place	1	2 **(Skip to E2)**
	1. Please specify: _____		

These questions ask about your 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.

E2. In the past year, how many times did you see a health care provider? Include wellness visits, sick visits, and ER/urgent care visits. **Do not include** times when you were hospitalized overnight.

___ ___ times

Don't Know..... -8

E3. In the past year, when you went for medical care, did you usually (more than half of the time) see the same health care provider or group of providers for your medical appointments?

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

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.

E4. In the past year, have you been hospitalized? Do not include overnight stays in the emergency room.

Yes 1
No ..... 2 **(Skip to E5)**
Don't Know ..... -8 **(Skip to E5)**

a. How many different times were you hospitalized in the past year?
___ ___ times

Don't Know ..... -8

These questions ask some questions about care or social services that you may have received in the past year.

E5. In the past year, have you been seen by a social worker or a case manager to help you obtain services?

Yes 1
No 2

E6. In the past year, have you received care or services from a psychologist, psychiatrist, psychiatric nurse, counselor, or other mental health professional?

Yes 1
No 2

E7. In the past year, has an agency assisted you with food, such as food stamps or WIC, meals on wheels, or food pantries)?

Yes 1
No 2

E8. In the past year, has a social service agency helped you find a place to live?

Yes 1
No 2

E9. In the past year, have you received care from a dentist or dental hygienist?

Yes 1
No 2

E10. In the past year, have you seen a nutritionist or a dietician?

Yes 1
No 2

SECTION F: HEALTH INSURANCE

These questions ask about your health care coverage.

F1. In the past year, has your health insurance changed?

Yes 1
No 2

F2. Do you currently have any kind of health insurance or health care coverage? This includes both private and government/state insurance programs (e.g., Medicaid, SCHIP, MCHIP or other public insurance), dental insurance, and programs that help pay for medications.

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

F3. How long has it been since you last had ANY health insurance or coverage?

6 months or less ..... 1 **(skip to F13)**
More than 6 months, but no more than 1 yr ago..... 2 **(skip to F13)**
More than 1 year, but no more than 3 years ago..... 3 **(skip to F13)**
More than 3 years..... 4 **(skip to F13)**
Never had health insurance or coverage..... 5 **(skip to F13)**
Don't know..... -8 **(skip to F13)**

F4. Do you have private insurance?

Yes 1
No 2

a. Do you or your family members pay for any of the insurance premium?

Yes 1
No 2

F5. Do you have government/state (Medicaid, SCHIP, MCHIP or other public) insurance?

Yes 1
No 2

F6. In the past year, was there any time when you were <u>not</u> covered by ANY health insurance or coverage?

Yes 1
No ..... 2 **(Skip to F7)**

a. In the past year, how long were you without ANY health insurance or coverage?

__ __ 1 = months 2 = weeks 3 = days

Do you have	<u>YES</u>	<u>NO</u>	
F7. Dental Insurance?	1	2	
F8. Vision Insurance?	1	2	
F9. Other* types of health insurance?	1	2	**(Skip to F10)**

Examples of other types of insurance include disability health insurance, long-term care insurance, critical illness insurance, accident insurance.

a. Specify, Other type of health insurance: _____

F10. Does your health insurance(s) help pay for prescriptions/medications?
Yes 1
No 2

F11. Does your health insurance plan(s) help pay for both doctor visits and hospital stays?
Yes 1
No 2
Don't Know..... -8

F12. In the past year, have you had difficulty filing insurance claims and/or getting reimbursed for medical care?
Yes 1
No 2
Don't Know..... -8

F13. In the past year, have you been without needed prescription medication due to cost?
Yes 1
No 2
Don't Know..... -8

F14. In the past year, how much of a problem was it to get care that you or a doctor believed necessary?
A big problem 1
A small problem 2
No problem..... 3
I had no visits in the last year..... -1
Don't Know..... -8

SECTION G: KIDNEY REPLACEMENT THERAPY DISCUSSION

The next questions ask about discussions you may have had with your nephrologist or healthcare provider. Remember, the terms "you" and "your" refers to the CKiD participant.

G1. In the past year, have you talked about kidney replacement therapy (i.e., dialysis or transplantation) with your nephrologist or healthcare provider?
Yes 1
No ..... 2 **(END)**

a. Did you talk about kidney replacement therapy **specifics** (i.e., modality, preference, etc.) with your nephrologist?
Yes 1
No ..... 2 **(END)**

G2. Have you talked about dialysis?
Yes 1
No ..... 2 **(skip to G4)**

G3. What type of dialysis was planned?
Hemodialysis (cleansing the blood outside of the body) 1
Peritoneal dialysis (cleansing the blood using the patient's own tissues inside the body) 2
No Decision Yet..... 9
Don't know..... -8

G4. Have you talked about kidney transplant?
Yes 1
No ..... 2 **(Skip to H1)**

G5. Which donor option(s) has/have been discussed?

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

	Yes	No	Don't Know
Living Donor……..	1	2	-8
Transplant Wait List/Deceased Donor…	1	2	-8

G6. Have you been listed for deceased donor transplantation, in other words, are you on a transplant waiting list?

Yes ……..…..... 1
No ……..……..……..…..... 2 **(Skip to H1)**

The next questions about for the date you were placed on the "inactive" waitlist and/or "active" waitlist. Individuals on the active waitlist are ready for a transplant and can receive offers, while those on the inactive waitlist are temporarily not able to receive an organ but continue to gain wait time.

a. Date listed on the Inactive Waitlist: ___ ___/ ___ ___/ ___ ___ ___ ___
M M / D D / Y Y Y Y
Don't know……-8

b. Date listed on the Active Waitlist: ___ ___/ ___ ___/ ___ ___ ___ ___
M M / D D / Y Y Y Y
Don't know…… -8

SECTION H: TRANSITION TO ADULT CARE

The next questions ask about transition to an adult care provider.

H1a. Have you transitioned to adult care?

Yes……..…..... 1
No……..……..……..…..... 2 **(skip to Section I)**
Don't Know……..……. -8 **(skip to Section I)**

H1b. Have you transitioned to adult care in the past year?

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

H2. Using a scale of 1 – 5, where 1 is poor and 5 is great, how would you rate your overall transition to adult care?

Poor/Hard				Great/Easy
1	2	3	4	5

a. If you rated your transition as 2 or less, please specify the reason(s) why you felt the transition was poor/hard.

_____

H3a. Using a scale of 1 – 5, where 1 is not at all satisfied and 5 is very satisfied, how would you rate your overall satisfaction **with your adult nephrology provider/team**?

Not at all satisfied				Very satisfied
1	2	3	4	5

b. If you rated your satisfaction as 2 or less, please specify the reason(s) why you are unsatisfied.

_____

H4. Is your current **nephrology** provider/team considered?
Private practice (doctor's office not part of a hospital or university) 1
Affiliated (part) with a hospital or a university…….. 2
Don't Know……. -8

H5. In the past year, where have you gone to receive your nephrology care?
Provide the name and address for your **nephrology** care provider/team.
Name of Provider: _____

Location (address): _____

H6. In the past year, when you went for **nephrology care**, did you usually (more than half of the time) see the same health care provider or group of providers for your **nephrology** medical appointments?

Yes…….. 1
No…….. 2
Don't Know……. -8

SECTION I: KIDNEY REPLACEMENT THERAPY

I0. Visit type:	RFU Baseline Visit	(visit = 10)	1 **(Skip to Section I)**
	RFU Re-entry Baseline Visit	(visit = 1010)	2 **(Skip to Section I)**
	RFU Follow-up Visits	(visit > 10)	3
	RFU Re-entry Visit	(visit > 1010)	4
	RFU Abbreviated Visit	(visit > 10)	5
	Post KRT Baseline Visit	(visit = 510)	6 **(Skip to Section I)**
	Post KRT Re-entry Baseline Visit	(visit = 1510)	7 **(Skip to Section I)**
	Post KRT Follow-up Visit	(visit > 510)	8
	Post KRT Re-entry Follow-up Visits	(visit > 1510)	9
	Post KRT Abbreviated Visit	(visit > 510)	10

The next set of questions ask about your transplant and dialysis that have occurred.

I1. Have you ever had a kidney transplant?
Yes…… 1
No…… 2 **(Skip to I2)**
Don't Know…….. -8 **(Skip to I2)**

I1a. How many kidney transplants have you had?
One…….. 1
Two…….. 2
Three or More……..... 3
Don't Know……-8

I1b. Was your most recent kidney transplant from a living relative, a living non-relative, or from a deceased donor?
Living Donor – Related…… 1
Living Donor – Not Related…… 2
Deceased Donor…… 3
Don't Know…… -8

I1c. Date of Most Recent Kidney Transplant: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y
I Don't know/I'm not sure……-8

Please enter the date of your transplant. If you do not know the month or day, please enter the year. Otherwise, select "I Don't Know/I'm not Sure."

I1d. When you see your doctor about your kidney transplant, how does he/she say it's doing? If you have more than one kidney transplant, please answer based on your most recent transplant.

The kidney function is good/excellent…….... 1 **(Skip to I2)**

The kidney is OK but I might need another transplant or dialysis in the near future (in 1 year or so)…..……...…… 3

The kidney is not working well and I am on dialysis…….. 2

Don't know/I'm not sure..……..…….…… -8 **(Skip to I2)**

I2. Have you ever been on dialysis?

Yes……..……... 1
No……..…… 2 **(Skip to I3)**
Don't Know…….……..… -8 **(Skip to I3)**

I2a. What type of dialysis did you use most recently:

Hemodialysis (cleansing the blood outside of the body)… 1
Peritoneal Dialysis (cleansing the blood using the patient's own body tissues inside the body)……..…..……. 2
Don't Know……..…….. -8

I1b. Date Chronic* Dialysis Started:

___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y
I Don't Know/I'm Not Sure……..…….-8

For hemodialysis, please enter the date when you started 2 or more days a week for at least 3 months.

For peritoneal dialysis (PD), please enter the date when you started treatments 5 or more days a week for at least 3 months.

If you do not know the month or day, please enter the year. Otherwise, select "I Don't know/I'm not sure."

I1c. Are you currently receiving regularly scheduled dialysis therapy?

Yes……..…..…….. 1 **(END FORM)**
No…….…… 2
Don't Know……..……... -8

The next set of questions ask about your transplant and dialysis that have occurred since your last CKiD visit.

J1. Since your last CKiD visit, have you had a kidney transplant?

Yes……...…. 1
No…… 2 **(Skip to J2)**
Don't Know…….……... -8 **(Skip to J2)**

J1a. Was your recent kidney transplant from a living relative, a living non-relative, or from a deceased donor?

Living Donor – Related…… 1
Living Donor – Not Related…… 2
Deceased Donor…… 3
Don't Know…… -8

J1b. Date of Recent Kidney Transplant: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y
I Don't know/I'm not sure……-8

Please enter the date of your transplant. If you do not know the month or day, please enter the year. Otherwise, select "I Don't Know/I'm not Sure."

J1d. When you see your doctor about your kidney transplant, how does he/she say it's doing? If you have more than one kidney transplant, please answer based on your most recent transplant.

The kidney function is good/excellent…….. 1 **(Skip to J2)**
The kidney is OK but I might need another transplant or dialysis in the near future (in 1 year or so)…..…….…… 3
The kidney is not working well and I am on dialysis…….. 2
Don't know/I'm not sure..……..…….…. -8 **(Skip to J2)**

J2. Since your last CKiD visit, have you started dialysis treatment?

Yes……..……... 1
No……..……. 2 **(END FORM)**
Don't Know…….……..… -8 **(END FORM)**

J2a. What type of dialysis did you use most recently:
Hemodialysis (cleansing the blood outside of the body)… 1
Peritoneal Dialysis (cleansing the blood using the patient's own body tissues inside the body)……..……. 2
Don't Know……..…….. -8

J2b. Date Chronic* Dialysis Started: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y
I Don't Know/I'm Not Sure……..…….-8

For hemodialysis, please enter indicate the date when you started 2 or more days a week for at least 3 months.
For peritoneal dialysis (PD), please enter the date when you started treatments 5 or more days a week for at least 3 months.
If you do not know the month or day, please enter the year. Otherwise, select "I Don't know/I'm not sure."

J2c. Are you currently receiving regularly scheduled dialysis therapy?

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

J3. Name of provider and address of institution where dialysis treatment will be, was or is performed:

_____

_____

_____

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 1 / 0 1 / 2 5

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 A8)**
Post-Transplant Visit…… 2 **(Skip to A8)**

A7. Is this study visit an irregular (accelerated) visit?
Yes…… 1
No…… 2

A8. Is this a baseline 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
N/A…… -1

A14. Has consent to store biological specimen(s) been obtained?
Yes…… 1
No…… 2
N/A…… -1

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
Temporal artery..... 4

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. Participant 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. Participant 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 unable to stand?

Yes..... 1 **(Skip to D5)**

No..... 2

D3. Participant 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. Participant 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 participants may be irritable during the study visit. Therefore, it may be difficult to measure blood pressure while the participant is awake. In such cases, blood pressure readings should be performed while the participant 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..... 1
Child..... 2
Adult..... 3
Large Adult..... 4
Thigh..... 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 PARTICIPANT'S ARM FOR 15 SECONDS (MAKE SURE THE PARTICIPANT 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: ___ ___ ___

SECTION F: EDEMA

F1. Edema**…..** ___
(Enter highest code. Code 0=none, 1=facial, 2=pretibial, 3=above knee, 4=presacral, 5=ascites, 6=anasarca)

SECTION G: PROBLEMS

G1. 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 G2)**

No……... 2 **(END HERE)**

G2. 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:** Edema……..…….....	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: 0 1 / 0 1 / 2 5

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 you are a child/young adult participant 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.

Deleted B1, B1a and B1b

B2. Do you 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, do you 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
Don't Know..... -8

Deleted B4 and B5

SECTION C: FOOD INSECURITY

The next questions are about your food situation in the past 12 months. Please respond whether the statement was often true, sometimes true, rarely true or never true for (you/your household).

C1. Within the past 12 months, we worried whether our food would run out before we got money to buy more.

Often true..... 1
Sometimes true..... 2
Rarely true..... 3
Never true..... 4

C2. Within the past 12 months, the food we bought just didn't last and we didn't have money to get more.

Often true..... 1
Sometimes true..... 2
Rarely true..... 3
Never true..... 4

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

Chronic Kidney Disease in Children

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.

CKiD Chronic Kidney Disease in Children

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

Chronic Kidney Disease in Children

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 Comments:	1 = right 2 = left	___ ___ . ___	1 = maximal 2 = questionable
D2.	Grip Test #2 Comments:	1 = right 2 = left	___ ___ . ___	1 = maximal 2 = questionable
D3.	Grip Test #3 Comments:	1 = right 2 = left	___ ___ . ___	1 = maximal 2 = questionable
D4.	Grip Test #4 Comments:	1 = right 2 = left	___ ___ . ___	1 = maximal 2 = questionable
D5.	Grip Test #5 Comments:	1 = right 2 = left	___ ___ . ___	1 = maximal 2 = questionable
D6.	Grip Test #6 Comments:	1 = right 2 = left	___ ___ . ___	1 = maximal 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 No..... 2 (END)	__ __ __	Yes..... 1 No..... 2 (END)	Yes..... 1(END) 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 No..... 2 (END)	___ ___ ___	Yes..... 1 No..... 2 (END)	Yes..... 1(END) 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**

Chronic Kidney Disease in Children Cohort Study (CKiD)

FOLLOW-UP VISIT

QUESTION BY QUESTION SPECIFICATIONS

SPECIMEN COLLECTION FORM for In-Person Visit (Form SC01)

This form is designed to collect information about the blood draw. This form should be completed by clinic staff (nurse or study coordinator), not laboratory staff.

SECTION A: GENERAL INFORMATION

A1. Record the participant's I.D. number or affix label in space provided.

A2. The interviewer (study coordinator) should record the CKiD visit number (e.g., 02) the participant is attending. If there is any confusion as to what type of study visit the participant is attending, the interviewer should bring this to the attention of their clinical coordinating center project director for clarification before completing the form.

A3. The form version is pre-printed. Use the form version dated 01/01/25.

A4. Record the date of the visit - the month, day and year. Example: 03/01/2010

A5. Record interviewer's initials. Example: _K_ _I_ _D_

A6. Document the type of visit. If regular study visit, then circle "0". If post-dialysis visit, then circle "1" and if post-transplant visit, then circle "2".

Upon collection, urine, serum, and iohexol blood* (for CBL studies) should be shipped immediately to CBL.

If consent is obtained for biological sample, then serum, plasma, and urine should be batched.

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 six (6) months. For specific questions, contact your CCC prior to shipment.

*** DO NOT COLLECT URINE FOR POST DIALYSIS PARTICIPANTS**

¥ ONLY COLLECT BLOOD FOR IOHEXOL FOR POST TRANSPLANT PARTICIPANTS

± ONLY collect whole blood for NIDDK Biorepository, if the sample was not collected at V1 OR if the sample collected at V1 was inadequate.

SECTION B: PREGNANCY AND FIRST MORNING URINE COLLECTION

B1a. Record if the participant is completing cardiac CT and/or iohexol procedure(s) by "Yes" (Code 1) or "No" (Code 2). If no is recorded, then skip to **B2c.**

B1b. Record if the participant is a female (assigned at birth) of child-bearing potential by circling "Yes" (Code 1) or "No" (Code 2). If yes is recorded, refer to the **PROMPT** below. If no is recorded, then skip to **B3**.

PROMPT: QUESTION B2 IS FOR FEMALE PARTICIPANTS OF CHILD-BEARING POTENTIAL ONLY. URINE PREGRNANCY TEST DATE MUST FALL WITHIN 72 HOURS BEFORE STUDY VISIT DATE.

If performing iohexol and/or cardiac CT procedures, B2 MUST BE COMPLETED BEFORE IOHEXOL TESTING IS INITIATED OR CARDIAC CT PROCEDURE IS PERFORMED.

B2a. If the participant is a female of child-bearing potential, record urine pregnancy test date – the month, the day, and the year.

B2b. Indicate if urine pregnancy results were "Positive" (Code 1) or "Negative" (Code 2). If the test results are positive, **END** the study visit and complete the transitional form.

B2c. Record if the participant is completing a post dialysis study visit by "Yes" (Code 1) or "No" (Code 2). If yes is recorded, then skip to **Section C**.

B3a. The participant was instructed to collect a first morning urine sample at home. The urine sample must be collected in a sterile container that was provided to the family. If urine was not collected at home, collect sample at site. Circle "Yes" (Code 1) if the sample was collected, and **skip to sub-question c**. If sample was not collected, circle "No" (Code 2).

B3b. Specify the reason for not obtaining the sample. Reason codes are provided in the gray area above: Not Required (Code1), Difficult Urine Collection (Code 2), Participant Refused (Code 3), Red Blood Cell Contamination (Code 4), Inadvertently Destroyed (Code 5) , Oversight (Code 6), and Insufficient Volume (Code 7). **Skip to B4**.

B3c. i. Record if the sample is a first morning urine sample. Circle "Yes" (Code 1) or "No" (Code 2).
ii. Record the time the urine sample was collected. Circle "am" (Code 1) or "pm" (Code 2).

OPTIONAL TESTS: LOCAL LAB TESTS (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)

B4. Performing a urine protein to creatinine ratio assay is OPTIONAL. Record if the urine protein to creatinine ratio assay was performed at the clinical site's local laboratory. Circle "Yes" (Code 1) if the assay was performed, and then **complete the Local Urine Assay Results Form L06** if the local labs are CLINICALLY INDICATED, as outlined above. Circle "No" (Code 2) if the assay was not performed.

URINE COLLECTION AND PROCESSING FOR REPOSITORY

PLEASE REFER TO TABLE B2

For further details pertaining to collection and processing, refer to Section 11 of the Manual of Procedures (MOP).

B5. Indicate whether the participant consented to have biological samples (i.e., serum, plasma, and urine) stored at the NIDDK Biorepository by circling "Yes" (Code 1) or "No" (Code 2). If "No" is selected, **END** the form.

B6a. Indicate whether the urine sample for the NIDDK Biorepository was obtained. Circle "Yes" (Code 1) if the sample was collected and skip to sub-question c. If sample was not collected, circle "No" (Code 2).

B6b. Specify reason for not collecting the sample by referring to the reason code list provided in the gray area above. **Skip to C1**.

B6c. After centrifuging, decant (pour off) the supernate (liquid reaction) into (7) 10 mL urine cryovials. **Although the sediment normally migrates to the bottom of the tube, the sediment may not be visible after centrifuging the urine.** Pour no more than 9 mL of urine into each 10 mL cryovial to allow for expansion. Promptly freeze samples and store at -70°C or lower. **Again, refer to Section 11 of the Manual of Procedures for further details.** The urine may be batched with the serum and plasma and shipped every four months to the NIDDK Biorepository.

Record if the supernate was decanted into urine transport cryovials in sub-question i by circling "Yes" (Code 1) or "No" (Code 2). Record the date the urine was frozen in sub-question ii.

WHEN COLLECTING REPOSITORY SAMPLES, COMPLETE THE SM01 FORM.

For more information, refer to the "Electronic Shipping Manifest Information" located on the CKiD website Coordinator Resources page:
https://statepi.jhsph.edu/ckid/coordinator-resources

SECTION C: VISIT 2 BLOOD DRAW

Encourage fluids throughout the visit.

Blood can be collected according to your institutional guidelines and placed directly into the appropriate tubes or transferred into the appropriate tubes. Below are two options for drawing the blood. The exact quantities of blood to be drawn will depend on the specific visit.

OPTION 1: Place intravenous (IV) line using 18-22 gauge polyethylene catheters. Blood can be drawn into one - three 10 mL syringes or directly into the appropriate tubes via a vacutainer. If using syringes, transfer the appropriate amount of blood into the specific tubes. Once the blood samples have been collected, and iohexol has been infused, the IV line may be removed. A second IV or butterfly needles may be utilized to collect the B1 and B2 samples.

OPTION 2: Place one butterfly needle (18 – 23 gauge). Use tape to stabilize butterfly needle as needed for blood draw. Blood can be drawn into one - three 10 mL syringes or directly into the appropriate tubes via a vacutainer. If using syringes, transfer the appropriate amount of blood into the specific tubes. Once the blood samples have been collected, and iohexol has been infused, the butterfly needle may be removed. An IV or butterfly needles may be utilized to collect the B1 and B2 samples.

Please refer to Section 11 of the Manual of Procedures (MOP) for further details pertaining to the collection and processing procedures.

PROMPT: IF SUSPECTED BLOOD DRAW ADVERSE EVENT (i.e., infection), COMPLETE ADVERSE EVENT FORM

C1. Document the actual time of the Blood Draw. Circle “AM” (Code 1) or “PM” (Code 2).

C2. CBL chemistries (renal panel, uric acid, cystatin c, lipid panel)

C2a. Indicate whether the sample for CBL chemistries (renal/uric acid/cystatin c/lipid panel) was obtained. Circle “Yes” (Code 1) if the sample was collected, and skip to sub-question c. If sample was not collected, circle “No” (Code 2).

C2b. Specify the reason for not obtaining the samples by referring to the reason codes provided in the gray area above. **Skip to C3a**.

C2ci. Indicate the appearance of the serum after centrifuge. Circle “Grossly (dark red)” (Code 1), “Moderately (Red/Light Red)” (Code 2), “Slightly (Pink)” (Code 3), or “Not Hemolyzed (Yellow)” (Code 4).

C2cii. Record whether the participant fasted after midnight before the study visit. In order for the lipid panel results to be valid, the participant must fast before the blood draw. Circle “Yes” (Code 1) if the participant fasted, circle “No” (Code 2) if they did not fast before the study visit. ***If the participant did NOT fast, the lipid results will indicate that the participant did not fast.***

C3a. iPTH

C3a-a Record if the sample for iPTH was collected. Circle “Yes” (Code 1) if the sample was collected, and skip to sub-question c. If sample was not collected, circle “No” (Code 2).

C3a-b. Specify reason for not collecting the sample by referring to the reason code list provided in the gray area above. **Skip to C3b**.

C3a-c. After the sample is centrifuged, 0.5 mL of serum should be transferred into a red-cap cryovial and stored in a freezer at -70°C or lower. Record the date the serum was frozen.

C3b. Vitamin D

C3b-a Record if the sample for vitamin D was collected. Circle "Yes" (Code 1) if the sample was collected, and skip to sub-question c. If sample was not collected, circle "No" (Code 2).

C3b-b. Specify reason for not collecting the sample by referring to the reason code list provided in the gray area above. **Skip to C3c**.

C3b-c. After the sample is centrifuged, 0.5 mL of serum should be transferred into a red-cap cryovial and stored in a freezer at -70°C or lower. Record the date the serum was frozen.

C3c. T50

C3c-a Record if the sample for T50 was collected. Circle "Yes" (Code 1) if the sample was collected, and skip to sub-question c. If sample was not collected, circle "No" (Code 2).

C3c-b. Specify reason for not collecting the sample by referring to the reason code list provided in the gray area above. **Skip to C3d**.

C3c-c. After the sample is centrifuged, 0.5 mL of serum should be transferred into a red-cap cryovial and stored in a freezer at -70°C or lower. Record the date the serum was frozen.

C3d. Cardiac biomarkers

C3d-a Record if the sample for cardiac biomarkers was collected. Circle "Yes" (Code 1) if the sample was collected, and skip to sub-question c. If sample was not collected, circle "No" (Code 2).

C3d-b. Specify reason for not collecting the sample by referring to the reason code list provided in the gray area above. **Skip to C4**.

C3d-c. After the sample is centrifuged, 0.5 mL of serum should be transferred into a red-cap cryovial and stored in a freezer at -70°C or lower. Record the date the serum was frozen.

C4. FGF23

C4a. Indicate whether the plasma sample for FGF-23 was obtained. Circle "Yes" (Code 1) if the sample was collected and **skip to sub-question c**. If sample was not collected, circle "No" (Code 2).

C4b. Specify the reason for not obtaining the sample. Reason codes list is provided in the gray area above: Not Required (Code1), Difficult Blood Draw (Code 2), Participant Refused (Code 3), Red Blood Cell Contamination (Code 4), Inadvertently Destroyed (Code 5) and Oversight (Code 6). **Skip to C5a**.

C4c. After the sample is centrifuged, 0.5 mL of plasma should be transferred into a cryovial with a green cap insert. Place sample in a freezer at -70°C or lower as soon as possible. **Again, refer to Section 11 of the Manual of Procedures for further details.** Record the date the serum was frozen. The serum should be batched and shipped to the CBL quarterly during the months of January, April, July and October.

C5a. Local CBC

C5a-a. Record if sample for local CBC was collected. Circle "Yes" (Code 1) if the sample was collected, and **skip to sub-question C5b**. If sample was not collected, circle "No" (Code 2).

C5a-b. Record the reason why the sample was not collected by referring to the reason code list provided in the gray area above. **Skip to C5b**.

C5a-c. THERE ARE NO ADDITIONAL REQUIREMENTS.

C5b. Local Renal Panel

C5b-a. Record if sample for local Renal Panel was collected. Circle "Yes" (Code 1) if the sample was collected, and **skip to sub-question C6**. If sample was not collected, circle "No" (Code 2).

C5b-b. Record the reason why the sample was not collected by referring to the reason code list provided in the gray area above. **Skip to C6**.

C5b-c. THERE ARE NO ADDITIONAL REQUIREMENTS.

Sites can obtain results for lab values that have been identified as "KEY VARIABLES". To obtain results, go to 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. Indicate whether the participant consented to having samples stored at the NIDDK Biorepository. Circle "Yes" (Code 1) if the consent was obtained. If consent was not obtained **Skip to C9**.

C7. Serum sample for NIDDK Biorepository

C7a. Indicate whether the serum sample for the NIDDK Biorepository was obtained. Circle "Yes" (Code 1) if the sample was collected and skip to sub-question c. If sample was not collected, circle "No" (Code 2).

C7b. Specify reason for not collecting the sample by referring to the reason code list provided in the gray area above. **Skip to C8**.

C7c. After the sample is centrifuged, 6 mL of serum should be transferred into a clear top cryovial for participants < 30 kg and 10 mL of serum should be transferred into a clear top cryovial for participants $\geq$ 30 kg. Place sample in a freezer at -70°C or lower as soon as possible. **Again, refer to Section 11 of the Manual of Procedures for further details.** Record the date the serum was frozen. The serum may be batched and shipped every four months to the NIDDK Biorepository.

C8. Plasma sample for NIDDK Biorepository

C8a. Indicate whether the plasma sample for the NIDDK Biorepository was obtained. Circle "Yes" (Code 1) if the sample was collected and skip to sub-question c. If sample was not collected, circle "No" (Code 2).

C8b. Specify reason for not collecting the sample by referring to the reason code list provided in the gray area above. **Skip to C9**.

C8c. After the sample is centrifuged, 3.0 mL of plasma should be transferred into a 3 mL cryovial with a green cap insert for participants < 30 kg and 5.0 mL of plasma should be transferred into 2 x 3 mL cryovials with a green cap insert for participants ≥ 30 kg. Place sample in a freezer at -70°C or lower as soon as possible. **Again, refer to Section 11 of the Manual of Procedures for further details.** Record the date the plasma was frozen. The plasma may be batched with the serum and shipped every four months to the NIDDK Biorepository.

Note: If applicable, any extra serum and/or extra plasma that is collected should be transferred into the extra cryovials provided. The extra serum should be transferred into the clear top cryovial marked "NIDDK BR SERUM" and the extra plasma should be transferred into the green cap insert marked "PLASMA (Extra)."

C9. Indicate whether the participant consented to have whole blood stored at NIDDK Biorepository by circling "Yes" (Code 1) or "No" (Code 2). If "No" is selected, **Skip to D1**.

C10. Whole Blood Sample

C10a. Indicate whether the whole blood sample for NIDDK Biorepository was obtained. Circle "Yes" (Code 1) if the sample was collected and **skip to sub-question c**. If sample was not collected, circle "No" (Code 2).

C10b. Specify the reasons for not obtaining the sample and **skip to D1**. Refer to the codes listed in the gray area above.

C10c. For "i", document the date of the blood draw. For "ii", document the initials of the person who performed the blood draw. For "iii", document the gender of the child. For "iv", document the age of the child. **Be sure the age is documented in years, not months.**

COPY PAGE 4 OF THE SPECIMEN COLLECTION FORM AND SEND TO NIDDK BIOREPOSITORY WITH A COPY OF THE SHIPMENT TRACKING FORM (ST04) AND WHOLE BLOOD SPECIMEN.

SECTION D

D1. Document the type of visit. If regular study visit, then circle "0" and **END FORM**. If post-dialysis visit, then circle "1" and **skip to Section G**. If post-transplant visit, then circle "2" and proceed to D2.

D2. Record if the participant is completing an iohexol study visit by circling "Yes, consent obtained" (Code 1) or "No" (Code 2). If "**No**" is selected, **END FORM.**

SECTIONS E & F SHOULD ONLY BE COMPLETED,
FOR POST-TRANSPLANT PARTICIPANTS COMPLETING IOHEXOL STUDY VISIT.

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

E1a-b. Indicate infusion syringe weight with Iohexol pre-infusion and post-infusion in grams.
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.

NOTE: Post-infusion weight should be **at least 6.0 g** less than the Pre-infusion weight. If the Post-infusion weight is not at least 6.0 g less, please confirm it.

PRE AND POST SYRINGE WEIGHT MUST BE OBTAINED IN ORDER TO CALCULATE THE PARTICIPANT'S GFR.

SECTION F: IOHEXOL

Refer to GFR Blood Draw Flow Chart on page 11 of SC01 and Section 11 of the Manual of Procedures for detailed instruction for Iohexol infusion and GFR blood draws.

- **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

F1a.	Document the infusion start time on the clock, and circle "AM" (Code 1) or "PM" (Code 2). **SET TIMER TO ZERO** and start Iohexol infusion.

- ***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. PLACE IN THE PROVIDED SST.***
- ***PROVIDING 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 1mg/kg Benadryl IV (maximum dose: 50 mg Benadryl IV) or follow your local institution guidelines.**
- **In the rare even 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 2mg/kg Solumedrol IV for administration as ordered by physician or follow your local institution guidelines.**

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)

F2a. This section documents the participant's post-infusion vitals. For sub-question a, record participant's blood pressure. For sub-question b, record their temperature and circle "1" for Celsius (°C) or "2" for Fahrenheit (°F). The normal body temperature range in Celsius is 36.1°C - 38.3°C or 94.5°F -100.6°F. For sub-question c, document post-infusion number of heart beats per minute. For sub-question d, record number of respirations per minute.

F3a. **B1** corresponds to blood draw at time = 2 hours (120 minutes.)

i) Indicate the actual time on timer.
ii) ONLY if Timer malfunctions, record Clock Time using the same clock used for G1a.
iii) Indicate whether it was a difficult blood draw. If "Yes" (Code 1) is chosen, skip to sub question b.
iv) Indicate if blood was drawn from a venipuncture.
v) Record the volume of blood that was collected.
vi) Indicate whether the sample was centrifuged by selecting "Yes" (Code 1) or "No" (Code2) and **skip to F4a**.

F3b. **B1** 2nd attempt of blood draw at time = 2 hours (120 minutes.)

i) Indicate the actual time on timer.
ii) ONLY if Timer malfunctions, record Clock Time using the same clock used for G1a.
iii) Indicate whether it was a difficult blood draw.
iv) Indicate if blood was drawn from a venipuncture.
v) Record the volume of blood that was collected.
vi) Indicate whether the sample was centrifuged by selecting "Yes" (Code 1) or "No" (Code2).

F4a. **B2** corresponds to blood draw at time = 5 hours (300 minutes.)

i) Indicate the actual time on timer.
ii) ONLY if Timer malfunctions, record Clock Time using the same clock used for G1a.
iii) Indicate whether it was a difficult blood draw. If "Yes" (Code 1) is chosen, skip to sub question b.
iv) Indicate if blood was drawn from a venipuncture.
v) Record the volume of blood that was collected.
vi) Indicate whether the sample was centrifuged by selecting "Yes" (Code 1) or "No" (Code2) and **END form.**

F4b. **B2** 2nd attempt of blood draw at time = 5 hours (300 minutes.)

i) Indicate the actual time on timer.
ii) ONLY if Timer malfunctions, record Clock Time using the same clock used for G1a.
iii) Indicate whether it was a difficult blood draw.
iv) Indicate if blood was drawn from a venipuncture
v) Record the volume of blood that was collected.
vi) Indicate whether the sample was centrifuged by selecting "Yes" (Code 1) or "No" (Code 2).

SECTION G: LOCAL KT/V

G1. Indicate whether local Kt/V results are available. Circle “Yes” (Code 1) if results are available, and then **skip to G2.** If these results are not available, circle “No” (Code 2), and proceed to G1a to specify reason.

G1a. Specify why Kt/V results are not available, and then **END FORM.**

G2. Record the date of the most recent available Kt/V results in month, day and then year format. Example: 03/01/2006

G3. Indicate which modality of dialysis the participant is currently receiving. Circle “Hemodialysis” (Code 1), if participant is receiving hemodialysis. If participant is receiving peritoneal dialysis, circle “Peritoneal dialysis” (Code 2), and **skip to G5.**

G4. Hemodialysis

G4a. If participant is receiving hemodialysis, report their urea reduction ratio (URR), in percent.

G4b. If participant is receiving hemodialysis, report their total Kt/V, then **END FORM.**

G5. Peritoneal dialysis (PD)

G5a. If participant is receiving peritoneal dialysis, report their peritoneal dialysis (PD) Kt/V.

G5b. If participant is receiving peritoneal dialysis, report their 24-hour urine volume.

G5c. If participant is receiving peritoneal dialysis, report their urine Kt/V.

G5d. If participant is receiving peritoneal dialysis, report their Total Kt/V, which is equal to PD Kt/V plus urine Kt/V (G5a + G5c), then **END FORM.**

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 1 / 0 1 / 2 5

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 10^3uL.	
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 (x10^6uL)

c. Platelet Count (PLTs) |___|___|___| (K/cu mm) or (x10^3uL)

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 1 / 0 1 / 2 5

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

FOR USE BY THE CBL ONLY

CENTRAL LABORATORY – RENAL PANEL TESTS

FORM L05

B3. **Renal Panel Blood Results**

a.	Urea Nitrogen (BUN)	|___|___|___|	(mg/dL)
b.	Calcium (CA)	|___|___| . |___|	(mg/dL)
c.	Chloride (CL)	|___|___|___|	(mmol/L)
d.	Carbon Dioxide (CO_2)	|___|___|	(mmol/L)
e.	Serum Creatinine	|___| . |___| |___|	(mg/dL)
f.	Glucose (GLU)	|___|___|___|	(mg/dL)
g.	Potassium (K)	|___| . |___|	(mmol/L)
h.	Sodium (NA)	|___|___|___|	(mmol/L)
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	|___|___| . |___| |___|	(g/L)

Enter "-1" for post-transplant visit participants

c.	Microalbumin	|___|___| . |___| |___|	(mg/L)

FOR USE BY THE CBL ONLY

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: **1 1 / 0 1 / 2 1**

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
Advanced Research and Diagnostic Laboratory (ARDL) 2

B2b. Assay

Mass Spectrometry..... 1
High Performance Liquid Chromatography (HPLC) 2

FOR USE BY THE CBL ONLY

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: ___ ___ . ___ ___

FOR USE BY THE CBL ONLY

CENTRAL LABORATORY
Intact Parathyroid Hormone (iPTH)
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 1 / 0 1 / 2 5

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 Results:**

a. (intact) Parathyroid (iPTH) |___||___||___| . |___| (pg/mL)

b. High Sensitivity C-Reactive Protein (hs CRP) Discontinued in 2024

FOR USE BY CBL ONLY

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 1 / 0 1 / 2 5

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)

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 1 / 0 1 / 2 5

*Prior to 01/01/25, samples were frozen and shipped in batches. As of the 2024 protocol amendment, cystatin C samples are collected and shipped at room temperature.

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/Rochester…….. 1
CMH…….. 2
CMH and CBL/Rochester…. 3
CBL/ARDL…….. 4

B4. Was IFCC standard used?

Yes, IFCC standard used.....1
No, IFCC standard was not used 2

B4a. Which assay?

Gentian…….. 1

B5. Serum Cystatin C – CBL |___| |___| . |___| |___| (mg/L)

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

FOR USE BY TRIAL CLINIC

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)

FOR USE BY THE CEL ONLY

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 8 / 0 1 / 2 1

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/PARENT OR OTHER ADULT:

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 the person completing the form 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 in the 1st grade, kindergarten or pre-school/pre-K, then enter "0". If the participant is currently in the 12th grade, then enter "11", if participant is a sophomore in college, then enter "13"or if the participant is currently in the 6th grade, then enter "5". In addition, if completed high school enter "12 years", if completed 4-year college degree enter "16 years", and if completed a 4-year doctoral degree enter "20 years."

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 **(skip to D10)**	2	-1 **(skip to D10)**	-8 **(skip to D10)**
Student.....	1 **(skip to D10)**	2	-1 **(skip to D10)**	-8 **(skip to D10)**
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 8 / 0 1 / 2 1

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/PARENT OR OTHER ADULT:

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) or that (*name of participant*) should take medicine to lower blood pressure?

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

a. What is the status of (*name of participant's*) high blood pressure (i.e., hypertension)?

Taking medicine but BP still high (Continued problem) 1
No longer has high blood pressure (Resolved problem) 2
Taking medicine and BP no longer high (Controlled w/ meds) 3

b. Was the high blood pressure (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?

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

MEDICAL HISTORY (MH)

(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 C12)**	-8 **(Skip to C12)**
	Specify:_____			

MEDICAL HISTORY (MH)

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 (not a part of a hospital building)	1	2
b.	A private doctor's office (not a part of a clinic or hospital)	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 G16)**
More than 6 months, but no more than 1 yr ago..... 2 **(skip to G16)**
More than 1 year, but no more than 3 years ago..... 3 **(skip to G16)**
More than 3 years..... 4 **(skip to G16)**
Never had health insurance or coverage..... 5 **(skip to G16)**
Don't know..... -8 **(skip to G16)**

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)**		

G16. Do any of these plans help pay for 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) help 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 insurance 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 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 no 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 no 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 no 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 no 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 no 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 no visits in the last year	-1
Don't Know	-8

SECTION H: KIDNEY REPLACEMENT THERAPY

H1. Have you ever discussed dialysis or kidney 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 dialysis or kidney transplant with your nephrologist or health care provider?

Yes 1
No 2

a. Did you discuss the type of dialysis (hemodialysis or peritoneal) or who would donate a kidney (living or deceased donor) with your nephrologist?

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

H3. Was dialysis discussed?

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

H4. Which type of dialysis is preferred?

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

H5. Was kidney transplantation discussed?

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

H6. Which kidney 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: 1 = Interviewer Assisted
(Circle "1", "2" or "3") 2 = Self-Administered
3 = Both

OVERALL PHYSICAL ACTIVITY (F17)

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 2 / 1 5 / 1 5

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

OVERALL PHYSICAL ACTIVITY (F17)

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?

___ hr ___ ___ mins

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**?

___ hr ___ ___ mins

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**?

___ hr ___ ___ mins

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**?

___ **hr** ___ ___ **mins**

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?

___ **hr** ___ ___ **mins**

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 8a

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 six (6) months. 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 (TRS03) 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 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 SST 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)**

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).

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

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: https://statepi.jhsph.edu/ckid/coordinator-resources/
Then, follow packaging instructions and ship to CBL with accompanying forms. **No FRIDAY shipments.** Ship

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: https://statepi.jhsph.edu/ckid/coordinator-resources/ 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. 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 C4)**	Date Frozen: ___ ___ / ___ ___ /___ ___ ___ ___ 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) or follow your local institution guidelines.

→ 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 or follow your local institution guidelines.

↓

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.

→ COMPLETE ADVERSE EVENT FORM and send to CCC for data entry

↓

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

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) or follow your local institution guidelines.**
- **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, or follow your local institution guidelines.**

(i) Post Vitals:		
F2a.	Post- infusion blood pressure:	___ ___ ___ / ___ ___ ___
b.	Post-infusion temperature:	___ ___ ___ . ___ 1 = ºC Typical range: **36.1 – 38.3** 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 8 / 0 1 / 2 1**

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**
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 six (6) months. 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".*

Complete the SM01 form, store sample(s) in freezer at -70ºC or lower, batch up to 40 samples and ship during **January, April, July and October**. **No Thursday/Friday shipments**. When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: https://statepi.jhsph.edu/ckid/coordinator-resources/. 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: https://statepi.jhsph.edu/ckid/coordinator-resources/
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)".*

Complete the SM01 form, 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**. **No Thursday/Friday shipments.** When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: https://statepi.jhsph.edu/ckid/coordinator-resources/ 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: https://statepi.jhsph.edu/ckid/coordinator-resources/ 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
				ii. Blood Drawn By : ____ ____ (initials)
				iii. Gender of participant : Male.....1 Female.....2
				iv. Age of participant : ____ ____ years

B5. Did the participant consent to have biological samples (i.e., serum, plasma, and urine) 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

SPECIMEN COLLECTION FORM for Visit 1b (L02)

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 protease inhibitor 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, complete the SM01 form and 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: https://statepi.jhsph.edu/ckid/coordinator-resources/ Then, follow packaging instructions. **No Thursday/Friday shipments.**

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	___ ___ **(END FORM)**	i. Was supernate decanted into urine transport cryovials? Yes.....1 No.....2 ii. Date Frozen: ___ ___ /___ ___ /___ ___ ___ ___ M M D D Y Y Y Y

SPECIMEN COLLECTION FORM for EVEN Follow-up Visits 2, 4, 6, 8, … (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 8 / 0 1 / 2 1**

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)**

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 six (6) months. 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 (TRS03) 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 **(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 2, 4, 6, 8, … (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) 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 (1) Tiger-Top SST 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 SST 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: https://statepi.jhsph.edu/ckid/coordinator-resources/
Then, follow packaging instructions and ship to CBL with accompanying forms. **No FRIDAY shipments.**

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 green cap insert cryovial (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)."*

Complete the SM01 form, store sample in freezer at -70ºC or lower, batch up to 40 samples and ship on dry ice quarterly (**Jan, April, July and Oct)** to the NIDDK BR. **No Thursday/Friday shipments.** When shipper is needed, complete "NIDDK BR Dry Ice Shipper Request Form" on CKiD website: https://statepi.jhsph.edu/ckid/coordinator-resources/
Then, follow packaging instructions.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: https://statepi.jhsph.edu/ckid/coordinator-resources/ to notify the appropriate personnel from the CBL and the NIDDK BR.

SPECIMEN COLLECTION FORM for EVEN Follow-up Visits 2, 4, 6, 8, … (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 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.** 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 EVEN Follow-up Visits 2, 4, 6, 8, … (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 protease inhibitor 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, complete the SM01 form and promptly freeze and store sample(s) at -70ºC or lower. Batch samples and ship on dry ice at least quarterly (include maximum of 36 cryovials per shipper). When shipper(s) is needed, complete *"NIDDK Shipper Request Form"* on CKiD website: https://statepi.jhsph.edu/ckid/coordinator-resources/ Then, follow packaging instructions. **No Thursday/Friday shipments**.

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 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 → **(END FORM)**

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 visit.

↓

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) or follow your local institution guidelines.

→ 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, or follow your local institution guidelines.

↓

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) or follow your local institution guidelines.**
- **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, or follow your local institution guidelines.**

(i) Post Vitals:		
G2a.	Post- infusion blood pressure:	___ ___ ___ / ___ ___ ___
b.	Post-infusion temperature:	___ ___ ___ . ___ 1 = ºC Typical range: **36.1 – 38.3** 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 EVEN Follow-up Visits 2, 4, 6, 8, … (L21)

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 **END)**	2 **(END)**
b.	**B2** 2nd attempt:	___ **hr** ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1	2	1	2	___ . ___ mL	1	2

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 8a

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 six (6) months.
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 (TRS03) 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 (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

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)***

DRAFT

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"*

Complete the SM01 form, store sample in freezer at -70ºC or lower, batch up to 40 samples and ship on dry ice quarterly (Jan, April, July and Oct) to the NIDDK BR. **No Thursday/Friday shipments.** When shipper is needed, complete "NIDDK BR Dry Ice Shipper Request Form" on CKiD website: https://statepi.jhsph.edu/ckid/coordinator-resources/
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: https://statepi.jhsph.edu/ckid/coordinator-resources
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)".*

Complete the SM01 form, store sample in freezer at -70ºC or lower, batch up to 40 samples and ship on dry ice quarterly (Jan, April, July and Oct) to the NIDDK BR. **No Thursday/Friday shipments.** When shipper is needed, complete "NIDDK BR Dry Ice Shipper Request Form" on CKiD website: https://statepi.jhsph.edu/ckid/coordinator-resources
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: https://statepi.jhsph.edu/ckid/coordinator-resources 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 protease inhibitor 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, complete the SM01 form and 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: https://statepi.jhsph.edu/ckid/coordinator-resources . Then, follow packaging instructions. No Thursday/Friday shipments.

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 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 <u>WAS NOT</u> 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 ii. Blood Drawn By : ____ ____ (initials) iii. Gender of participant : Male.....1 Female.....2 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

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.** 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 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 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

CKiD 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:	___ ___ ___ . ___ 1 = ºC Typical range: **36.1 – 38.3** 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)**

CKiD Chronic Kidney Disease in Children

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

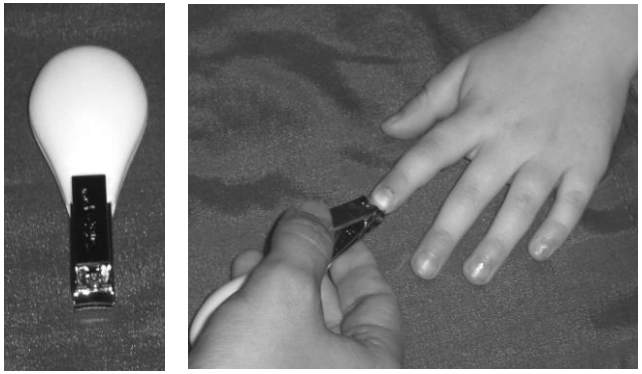


Figure B

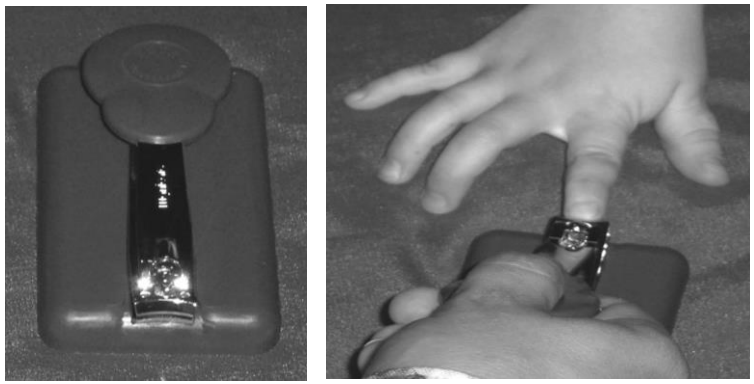
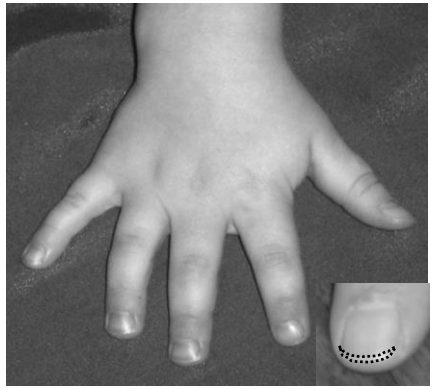


Figure C



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: _____

_____

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

FOR USE BY THE CLINIC

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)

FOR USE BY THE CBL ONLY