ADVERSE EVENT FORM
(ONLY COMPLETED If Study-Related Adverse Event within 24 Hours of Procedure)

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 NUMBER: ____ ____

A3. FORM VERSION: 0 6 / 0 1 / 0 8

A4. DATE OF ADVERSE EVENT: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. DATE FORM COMPLETED: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A6. FORM COMPLETED BY (INITIALS): ___ ___ ___

A7. Is this study visit an accelerated visit?
Yes..... 1
No..... 2

SECTION B: TYPE OF ADVERSE EVENT

B1. Suspected Iohexol Reaction?
Yes..... 1
No..... 2 **(Skip to B4)**

B2. Type of Suspected Iohexol Reaction

		Yes	No	
a.	Rash.....	1	2	
b.	Decreased Systolic Blood Pressure (more than 25 mmHg).....	1	2	
c.	Decreased Diastolic Blood Pressure (more than 20 mmHg).....	1	2	
d.	Increased Pulse (Heart Rate > 20 beats/min).....	1	2	
e.	Decreased Pulse (Heart Rate > 20 beats/min).....	1	2	
f.	Other.....	1	2	**(Skip to B3)**

i. Specify:_____
_____

B3. Please indicate the likelihood that the reaction was due to Iohexol.
Most Probably..... 1
Probably..... 2
Possibly..... 3
Probably Not..... 4

ADVERSE EVENT FORM
(ONLY COMPLETE If Study-Related Adverse Event within 24 Hours of Procedure)

B4. Suspected Blood Draw Adverse Event?

Yes..... 1
No..... 2 **(Skip to B7)**

B5. Type of Suspected Blood Draw Adverse Event

	Yes	No	
a. Infection.....	1	2	
b. Other.....	1	2	**(Skip to B6)**

i. Specify:_____

B6. Please indicate the likelihood that the adverse event was related to the blood draw.

Most Probably..... 1
Probably..... 2
Possibly..... 3
Probably Not..... 4

B7. Suspected ABPM Adverse Event?

Yes..... 1
No..... 2 **(Skip to B10)**

B8. Type of Suspected ABPM Adverse Event

	Yes	No	
a. Bruising.....	1	2	
b. Other.....	1	2	**(Skip to B9)**

i. Specify:_____

B9. Please indicate the likelihood that the adverse event was related to the ambulatory blood pressure monitor.

Most Probably..... 1
Probably..... 2
Possibly..... 3
Probably Not..... 4

B10. Did the adverse event result in a prolonged observational period or another type of adverse event?

	Yes	No
Prolonged observational period.....	1	2
Emergency room visit.....	1	2
Hospitalization	1	2
Other.....	1	2

i. Specify:_____

B11. Did the adverse event cause the participant to withdraw from the study?

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

PROMPT:
If a participant has a serious adverse event (SAE) related to a study procedure (i.e., iohexol GFR) within 24 hours of the procedure, the event must be reported within specified local IRB time guidelines to the local IRB. Please notify the Data Coordinating Center via fax at (410)-955-7587.

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

B3. IS THIS A MAKE-UP GFR VISIT?

Yes 1
No, ... 2
Don't know..... -8

SECTION C: IOHEXOL CONCENTRATIONS

C1. **B1** 10 min: ___ ___ ___ ___ . ___

C2. **B2** 30 min: ___ ___ ___ . ___

C3. **B3** 120 min: ___ ___ ___ . ___

C4. **B4** 300 min: ___ ___ ___ . ___

LOCAL LABORATORY – URINE ASSAY RESULTS
Form L06

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 / 0 6

A4. DATE FORM COMPLETED: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. FORM COMPLETED BY (INITIALS): ___ ___ ___

A6. Is this study visit an 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)

Chronic Kidney Disease in Children

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. CKiD VISIT #: ____ ____

A3. FORM VERSION: 0 7 / 0 1 / 0 8 a

ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.

SECTION B

B1. ARE TEST RESULTS AVAILABLE?

Yes ..... 1 **(B2)**
No, Sample Inadequate..... 2 **(END)**
No, Other Reason 3

_____ **(END)**
(SPECIFY)

B2. DATE SAMPLE DRAWN:

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

CENTRAL LABORATORY – RENAL PANEL TESTS

FORM L05

B3. **Renal Panel Blood Results**

a.	Sodium (NA)	|___|___|___|	(mmol/L)
b.	Potassium (K)	|___| . |___|	(mmol/L)
c.	Chloride (CL)	|___|___|___|	(mmol/L)
d.	Carbon Dioxide (CO_2)	|___|___|	(mmol/L)
e.	Urea Nitrogen (BUN)	|___|___|___|	(mg/dL)
f.	Serum Creatinine – Enzmatic	|___| . |___| |___|	(mg/dL)
g.	Glucose (GLU)	|___|___|___|	(mg/dL)
h.	Calcium (CA)	|___|___| . |___|	(mg/dL)
i.	Phosphate (PO_4)	|___|___| . |___|	(mg/dL)
j.	Uric Acid (Urate)	|___| . |___|	(mg/dL)
k.	Albumin (ALB)	|___| . |___|	(g/dL)

B4. **Urine Results**

a.	Creatinine, Urine	|___|___|___|	(mg/dL)
b.	Protein, Urine	|___|___|	(mg/dL)
c.	Microalbumin	|___|___| . |___| |___|	(mg/dL)

B5 a. Indicate the appearance of the serum |___|

Gross hemolysis..... 1
Moderate hemolysis..... 2
Slight hemolysis..... 3
No hemolysis..... 4

b. Was the assay run on or after November 7, 2007?

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

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 / 0 6

A4. DATE FORM COMPLETED: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. FORM COMPLETED BY (INITIALS):

___ ___ ___

A6. Is this study visit an 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

Chronic Kidney Disease in Children

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 – 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. CKiD VISIT #: ___ ___

A3. FORM VERSION: 0 1 / 0 1 / 0 7

A4. DATE FORM COMPLETED: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. FORM COMPLETED BY (INITIALS):

___ ___ ___

A6. Is this study visit an 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

Chronic Kidney Disease in Children

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 – BASIC METABOLIC 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. CKiD VISIT #: ___ ___

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

A4. DATE FORM COMPLETED: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. FORM COMPLETED BY (INITIALS):

___ ___ ___

A6. Is this study visit an 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

Chronic Kidney Disease in Children

B3. **Basic Metabolic 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)

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 6 / 0 1 / 0 8

A4. SPECIMEN COLLECTION DATE: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A5. FORM COMPLETED BY: (INITIALS) ___ ___ ___

The following sample should be collected.

Samples:	Shipped to:	Shipped:
Serum	CBL	BATCHED (Ship in Jan, Apr, Jul or Oct)

Please refer to questions 25 and 26 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)	Rutgers Repository	IMMEDIATELY
Nail Clippings (Biological)	NIDDK Biosample Repository	IMMEDIATELY
Hair (Biological)	NIDDK Biosample Repository	IMMEDIATELY
Serum (Biological)	NIDDK Biosample Repository	Batched (Jan, Apr, Jul or Oct)
Plasma (Biological)	NIDDK Biosample Repository	Batched (Jan, Apr, Jul or Oct)
Urine (Biological)	NIDDK Biosample Repository	Batched (Jan, Apr, Jul or Oct)

SECTION B: Visit 1B BLOOD DRAW

For Initial Blood Draw with Syringe, Vacutainer OR Butterfly Method:
Select the Type of Consent Obtained (options 1 through 4) That Pertain to the CKiD Participant:

1 **If participant consented to both BIOLOGICAL AND GENETIC samples:**

Collect 16.3 mL if participant is **< 30 kg** **OR** 20.3 mL if participant is **≥ 30 kg**.

If **< 30 kg**, immediately transfer **(using 18-22 gauge needle)** or draw:
- 7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository (**ACD Tubes must be COMPLETELY FILLED TO THE TOP**)
- 5.5 mL into (1) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 3 mL into (1) PST for NIDDK Biosample Repository

If **≥ 30 kg**, immediately transfer **(using 18-22 gauge needle)** or draw:
- 7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository (ACD Tubes must be COMPLETELY FILLED TO THE TOP)
- 7.5 mL into (1) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 5 mL into two (2) PSTs for NIDDK Biosample Repository

2 **If participant consented to BIOLOGICAL samples ONLY:**

Collect 8.5 mL if participant is **< 30 kg** **OR** 12.5 mL if participant is **≥ 30 kg**.

If **< 30 kg**, immediately transfer or draw:
- 5.5 mL into (1) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 3 mL into (1) PST for NIDDK Biosample Repository

If **≥ 30 kg**, immediately transfer or draw:
- 7.5 mL into (1) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 5 mL into two (2) PSTs for NIDDK Biosample Repository

3 **If participant consented to GENETIC samples ONLY:**

Collect 10.3 mL from all participants (regardless of weight)

Immediately transfer or draw:
- 7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository (ACD Tubes must be COMPLETELY FILLED TO THE TOP)
- 2.5 mL into (1) Tiger-Top SST for CBL

4 **If participant did NOT consent to BIOLOGICAL AND GENETIC samples:**
- Collect 2.5 mL from all participants (regardless of weight). Immediately transfer or draw 2.5 mL into (1) Tiger-Top SST for CBL.

SECTION B: Visit 1B BLOOD DRAW PROCESSING

PROCESSING BLOOD FOR CBL, NIDDK BR AND RUTGER SAMPLES

CBL & NIDDK BR (Serum)

Invert the Tiger Top SST 5-10 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 at 1100-1300g for 10 mins in swinghead OR 15 mins in fixed angle.
*If incomplete separation, centrifuge again 10-15 mins.

iPTH/wrCRP
Pipette 0.75 mL of serum into a red-top cryovial tube for CBL iPTH &, wrCRP

Vitamin D
Pipette 0.5 mL of serum into a 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 "iPTH/wrCRP/vitamin D Dry Ice Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ Then, follow packaging instructions and ship to CBL with accompanying forms. No FRIDAY shipments. Ship on next business day.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website to notify Paula Maier and Alicia Wentz that sample(s) have been shipped to CBL.

NIDDK (Serum)
Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) serum into clear top cryovial.
If there is any extra serum, then pipette the extra serum into the clear top cryovial marked "SERUM (Extra)".

Store sample(s) in freezer at -70ºC or lower, batch up to 40 samples and ship during **January, April, July and October**. When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/. Then, follow packaging instructions.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website to notify Heather Higgins, Sandra Ke and Alicia Wentz that sample(s) have been shipped to NIDDK BR.

NIDDK BR (Plasma)

Invert each PST 5-10 times gently to mix.

Centrifuge each PST at 1100-1300g for 10 mins (swinghead) **OR** 15 mins (fixed angle).

Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) plasma into cryovial with green cap insert.
If there is any extra plasma, then pipette the extra plasma into the green cap insert cryovial marked "PLASMA (Extra)".

Store sample(s) in freezer at -70ºC or lower, batch up to 40 samples and ship during the months of **January, April, July and October**. When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/. Then, follow packaging instructions.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website to notify Heather Higgins, Sandra Ke and Alicia Wentz that sample(s) have been shipped to NIDDK BR.

RUTGERS

Invert each of the 3 pediatric yellow-top ACD Tubes 6 times gently to mix blood with additives.

Keep tubes at room temperature. **DO NOT FREEZE.**

Follow packaging instructions and ship immediately to Rutgers Repository with accompanying forms. **Specimen can be shipped on Friday.**

Complete "On-line Shipping Form" on CKiD website to notify Alicia Wentz that sample(s) have been shipped to Rutgers. Also, notify Rutgers Repository by completing Shipping Blood log on Rutgers' website by clicking on the link: http://rucdr.rutgers.edu

SECTION B: Visit 1B BLOOD DRAW AND PROCESSING

B1. ACTUAL TIME OF BLOOD DRAW ____ ____ : ____ ____ 1 = AM 2 = PM

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:**
B2. Serum for iPTH, wrCRP & Vitamin D (2.5 mL of blood in Tiger Top SST)	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 Rutgers, the Genetic Repository?
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 Rutgers Cell & DNA Repository (7.8 mL of blood in 3 pediatric (2.6 mL) Yellow Top ACD tubes)	1 **(skip to c→)**	2	__ __ **(skip to B5)** **Deleted ii. Time of Collection**	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

COPY THIS PAGE **AND SHIPMENT TRACKING FORM (ST04) AND SEND TO RUTGERS WITH RUTGERS SPECIMEN.**

B5. Did the participant consent to have biological samples (i.e., serum, plasma, urine, nail clippings and hair samples) stored at NIDDK Biosample Repository?

Yes..... 1

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

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:**
B6. Serum for NIDDK Biosample Repository (**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 Biosample Repository (**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 children < 30 kg and 5.0 mL for children ≥ 30 kg

SECTION C: Visit 1B URINE COLLECTION AND PROCESSING FOR REPOSITORY

Collect FRESH urine into an initial urine collection cup or hat (provided by the site).

Pour 15-60 mL (preferably 60 mL) of FRESH urine into blue top 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 tablets are completely dissolved, pour urine into 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) for 10 mins (swinghead units) **– OR –** 15 mins (fixed angle units).

Decant (pour off) the supernates (liquid reaction) into 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 up to 36 samples quarterly. When shipper 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 Heather Higgins, Sandra Ke and Alicia Wentz 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

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 Biosample Repository (15.0 - 60.0 mL of urine in specimen container and transferred into collection cup with protease inhibitors)	1 **(skip to c→)**	2	___ ___ **(skip to D1)**	i. Was supernate decanted into urine transport cryovials? Yes.....1 No.....2 ii. Date Frozen: ____ ____ /___ ___ /___ ___ ___ ___ M M D D Y Y Y Y

SECTION D: NAIL CLIPPING COLLECTION

- Collection of fingernails is preferred. **DO NOT** collect fingernail clippings if the participant has acrylic nails, nail fungus, or discoloration causing pain or discomfort. If the participant cannot provide fingernail clippings, the Study Coordinator may clip the participant's toenails instead. **FINGERNAILS AND TOENAILS SHOULD NOT BE COLLECTED IN THE SAME CRYOVIAL** (collect one or the other).
- STAINLESS STEEL NAIL CLIPPERS MUST BE USED TO COLLECT NAIL CLIPPINGS. Use small (pediatric size) stainless steel nail clippers (see Figure A) for younger children 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) fingernails, removing approximately 1 millimeter from each nail (See Figure C). **Be prepared to collect flyaway nails.**
  - (To use nail clippers, see Figures A – D). Refer to CKiD MOP Section 12 for further details.
  - Carefully place the nail clippings into the cryovial (see Figure D). After using the nail clipper, spray the clipper with **SaniZide Plus** and wipe clean with clean cloth.

Figure A

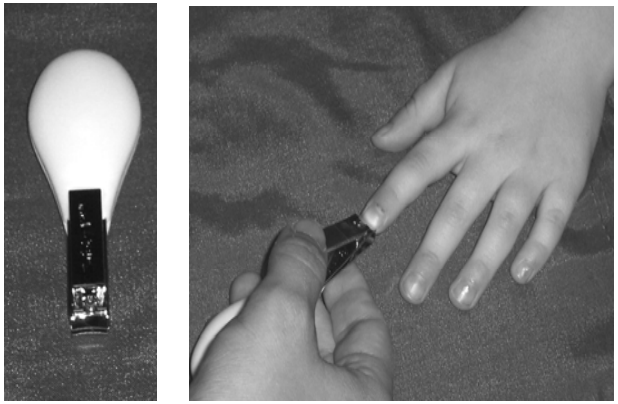


Figure B

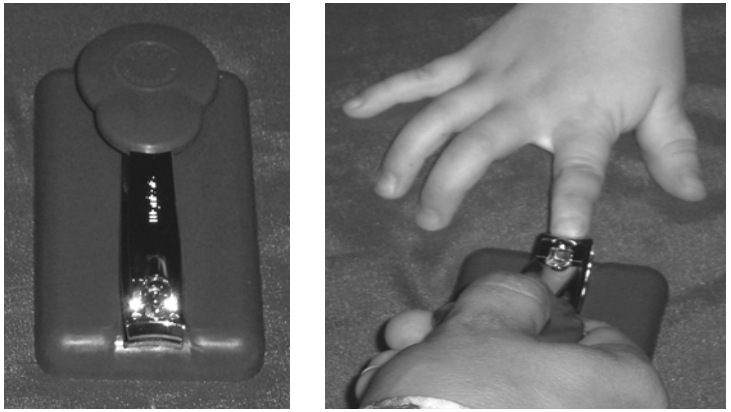
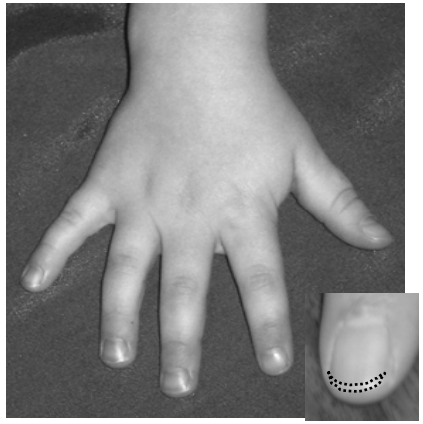
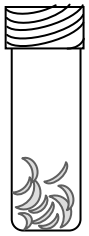


Figure C



Provide 10 nail clippings that are at least 1 mm tall

Figure D



D1. Does the participant have acrylic nails?

Yes..... 1 **(Skip to D3)**

No..... 2

D2. Were 10 fingernail clippings collected?

Yes..... 1 **(Skip to E1)**

No..... 2

a. How many fingernail clippings were collected?

___ ___

b. Specify reason "10" fingernail clippings were not collected.

Nails not long enough..... 1 **(Skip to D3)**

Participant Refused..... -7 **(Skip to D3)**

Other..... 2

i.
Specify:_____

_____

D3. Were 10 toenail clippings collected?

Yes..... 1 **(Skip to E1)**

No..... 2

a. How many toenail clippings were collected?

___ ___

b. Specify reason "10" toenail clippings were not collected: (e.g., Nail fungus or discoloration causing pain or discomfort)

Nail fungus or discoloration..... 1 **(Skip to E1)**

Nails not long enough..... 2 **(Skip to E1)**

Participant Refused..... -7 **(Skip to E1)**

Other..... 3

i. Specify:

_____

SECTION E: HAIR SAMPLE COLLECTION

- STAINLESS STEEL SCISSORS MUST BE USED TO COLLECT HAIR SAMPLE. The scissors are included in the CKiD starter package.
- DO NOT collect hair sample if the participant has colored, straightened or chemically altered hair
- Clean blades of stainless steel scissors with **SaniZide Plus** prior to use.
- Use powder-free gloves.
- Refer to CKiD MOP Section 12 for further details.
    - Lift up the top layer of hair from the **occipital** region of the scalp (see Figure A). Isolate a small thatch of hair (at least 20 fibers) from this region (see Figure B).
    - **Place the label with the participant's KID ID # tightly around all 20 strands of hair located at the distal end (furthest from the scalp)** (see Figure C).
    - Cut the hair sample off the participant's head **as close to the scalp as possible** (see Figure D).
    - Place cut thatch of hair inside aluminum foil (4 X 4) and fold the top of the foil to completely enclose the hair sample.
    - Place the aluminum foil inside a Ziplock bag (4 X 4) with the gel desiccant pellets in it and seal.
    - Store sample at room temperature in a dark place prior to shipment.
    - After using the scissors, spray scissors with **SaniZide Plus** and wipe clean with clean cloth**.**

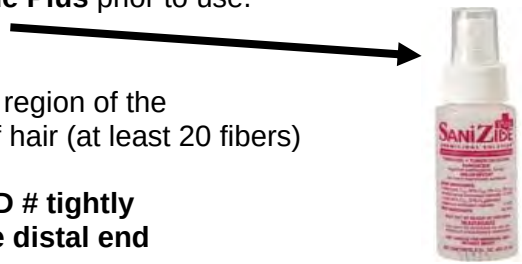
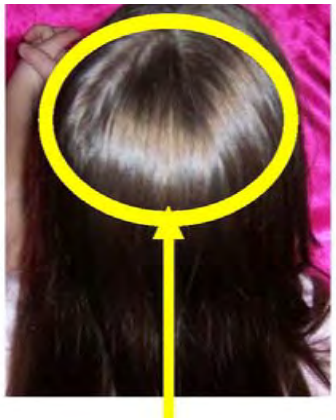


Figure A



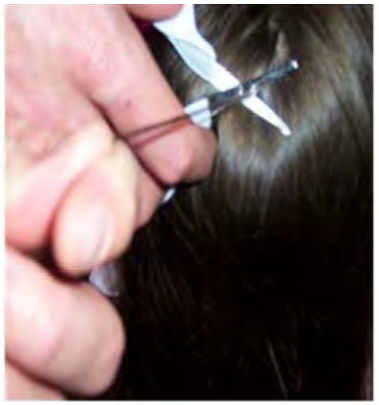
Occipital Region of Scalp

Figure B

Figure C

Place the KID ID label tightly around all 20 strands.

Figure D



Cut the hair sample off the participant's head *as close to the scalp as possible.*

E1. Does the participant have permed, dyed, colored, straightened or chemically altered hair?

Yes..... 1 **(END)**

No..... 2

E2. Was the Study Coordinator able to cut at least 20 fibers of hair from the **occipital** region?

Yes..... 1 **(END)**

No..... 2

a. Specify reason "20" hair fibers were not collected:

Hair not long enough..... 1 **(END)**

Participant Refused..... -7 **(END)**

Other..... 2

i. Specify:_____

_____

SPECIMEN COLLECTION FORM for 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 6 / 0 1 / 0 8

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

A5. FORM COMPLETED BY: (INITIALS) ___ ___ ___

The following samples should be collected.

Samples:	**Shipped to:**	**Shipped:**
Serum	**CBL**	**IMMEDIATELY**
Serum	**CBL**	**Batched** **(Ship in Jan, Apr, Jul or Oct)**
Iohexol Blood	**CBL**	**IMMEDIATELY**
Urine	**CBL**	**IMMEDIATELY**

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 GFR TESTING DATE.

B2. a. Urine pregnancy test date: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

b. Urine pregnancy results:

Positive..... 1 **(END; COMPLETE DISENROLLMENT FORM)**

Negative..... 2

B3. Is this study visit a Make-Up GFR visit?

Yes..... 1

No..... 2 **(Skip to B5)**

B3a. Make-up GFR date:

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

***MAKE-UP GFR VISIT* PROMPT: COLLECT 1.0 mL OF BLOOD IN THE PROVIDED SST LABELED B0 BEFORE THE IOHEXOL INFUSION.**

(Remember to waste 1cc if the blood was not collected from a butterfly.)

B4. Indicate reason(s) for a Make-Up GFR visit: **(Circle "Yes" or "No" for each):**

	Yes	No
IV infiltration.....	1	2
Inability to successfully draw 4 blood samples for iohexol.....	1	2
Other reason.....	1	2 **(Skip to E1)**

Specify:_____ **(Skip to E1)**

SPECIMEN COLLECTION FORM for Visit 1a (L01)

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 into a specimen container provided by the central biochemistry laboratory.

↓

Pour 10 to 14.5 mL of urine into dark blue top urine collection tube (provided by CBL).

↓

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
	2 = Difficult Urine Collection	4 = Collection 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:**
B5. Urine Creatinine, Urine Protein, Urine Albumin (10.0 mL–14.5 mL in Dark Blue Top tube)	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

Encourage fluids throughout the visit.

↓

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

↓

Complete Time=0 (Pre-Iohexol Infusion) blood draw according to MOP instructions/flowchart on page 4.
NOTE: If patient has had a local CBC drawn within the past 30 days, those CBC results may be used instead of drawing another CBC and blood draw amounts can be decreased by 1 ml.

SPECIMEN COLLECTION FORM for Visit 1a (L01)

SECTION C: PRE-IOHEXOL INFUSION (B0) BLOOD DRAW

Initial blood draw with **Syringe**: 12 mL

Immediately transfer 1 mL of whole blood into lavender-top tube for local CBC and 3 mL for local renal panel. Process and send to local lab for analysis and complete CBC and Local Renal Panel results forms (L04 & L03).

Using 18-22 gauge needle, immediately transfer remaining whole blood into tiger-top SST.

OR

Initial blood draw with **Vacutainer Method**: draw 1 mL directly into lavender-top tube for local CBC; draw 3 mL directly for local renal panel; draw 8 mL directly into tiger-top SST

OR

Initial blood draw with **Butterfly**: draw 1 mL directly into lavender-top tube for local CBC; draw 3 mL directly for local renal panel; draw 8 mL directly into tiger-top SST

Invert the SST 5-10 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 at MAX SPEED (between 1100-1300 g) 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 for Pre-Iohexol level. Also, if the sample is **GROSSLY HEMOLYZED (Dark Red),** collect 2.5 mL of additional blood at **B1**, **B2**, **B3** or **B4**. Centrifuge and then transfer serum into the extra Clear-Top with Red Ring Tube provided.

If sample is moderately, slightly or NOT HEMOLYZED, proceed with CBL preparation.

B0
Using the disposable pipette, pipette 0.5 mL of serum into Clear-Top with Red Ring Transport Tube labeled "B0" for B0 sample.

CBL Chemistries
Using the disposable pipette, pipette 3.0 mL of serum into Clear-Top with Red Ring Transport Tube labeled "Serum CBL" for CBL chemistries, Serum Creatinine, iron sample.

Cystanin 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 to CBL every four months. When shipper is needed, complete "Cystatin C 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

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.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ to notify Paula Maier and Alicia Wentz that sample(s) have been shipped to CBL.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ to CBL and Alicia Wentz that sample(s) have been shipped.

SPECIMEN COLLECTION FORM for Visit 1a (L01)

C1. ACTUAL TIME OF PRE-IOHEXOL INFUSION (B0) 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	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:**
C2. Renal/Iron Chemistries (7.0 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 (3.0 mL in Local SST)	1 **(skip to D2)** 2	___ ___ **(skip to D2)**	**N/A**

SPECIMEN COLLECTION FORM for Visit 1a (L01)

SECTION D: 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 1st morning 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: 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 CHILD'S GFR.

SECTION F: IOHEXOL – Refer to Instructions for Iohexol Infusion and GFR Blood Draws Flow Chart on Page 8

- **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

F1. IOHEXOL INFUSION

a. INFUSION START TIME: ____ ____ : ____ ____ 1 = AM 2 = PM

SPECIMEN COLLECTION FORM for Visit 1a (L01)

- **DO NOT DRAW BLOOD FROM THE IV SITE WHERE IOHEXOL WAS INFUSED. ANOTHER IV SITE MUST BE USED.**
- **COLLECT 1 mL of BLOOD FOR EACH IOHEXOL BLOOD DRAW AND TRANSFER INTO THE PROVIDED SST.**
- **RECORDING THE EXACT NUMBER OF MINUTES ON THE TIMER IS MORE IMPORTANT THAN DRAWING THE BLOOD EXACTLY AT 10, 30, 120 & 300 MINUTES AFTER IOHEXOL INFUSION. FOR EXAMPLE, IF BLOOD IS DRAWN AT 33 MINS INSTEAD OF 30 MINS, DOCUMENT BLOOD DRAWN @ 33 MINS.**
- **TIME SHOULD BE RECORDED IMMEDIATELY AFTER EACH BLOOD SAMPLE IS OBTAINED (i.e., B1, B2, B3, B4).**

ALL TIMES should be documented from the initial infusion time		**(i) ACTUAL MINUTES on TIMER**	(ii) **ONLY** if Timer malfunctions, record Clock Time using the same clock used for F1a	**(iii) Difficult Blood Draw: Yes**	**No**	**(iv) Blood Volume Collected (1 mL):**	**(v) Centrifuged at Clinical Site: Yes**	**No**
F2a.	**B1** 10 min:	___ ___ minutes	___ ___ : ___ ___ 1 = AM 2 = PM	1 **(Skip to b)**	2	___ . ___ mL	1 **(Skip to F3a)**	2 **(Skip to F3a)**
b.	**B1** 2nd attempt:	___ ___ minutes	___ ___ : ___ ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2

INVERT TUBE 5-10 TMES AFTER EACH BLOOD DRAW

LET SST TUBE STAND 20-30 MINUTES (BUT NO LONGER THAN 1 HOUR)

CENTRIFUGE AT 1100-1300 g (3000 rpm with 10 cm radius) FOR AT LEAST 10 MINS IN SWINGHEAD OR 15 MINS IN FIXED ANGLE

POST VITALS SHOULD BE TAKEN IMMEDIATELY AFTER THE 10 MINUTE BLOOD DRAW 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.**

SPECIMEN COLLECTION FORM for Visit 1a (L01)

(i) Post Vitals:		
F3a.	Post- infusion blood pressure:	___ ___ ___ / ___ ___ ___
b.	Post-infusion temperature:	___ ___ . ___ 1 = ºC 2 = ºF
c.	Post-infusion number of heart beats per minute:	___ ___ ___
d.	Post-infusion respirations per minute:	___ ___

	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 F1a	**(iii) Difficult Blood Draw: Yes**	**No**	**(iv) Blood Volume Collected (1 mL):**	**(v) Centrifuged at Clinical Site: Yes**	**No**
F4a.	**B2** 30 min:	___ ___ minutes	___ ___ : ___ ___ 1 = AM 2 = PM	1 **(Skip to b)**	2	___ . ___ mL	1 **(Skip to F5a)**	2 **(Skip to F5a)**
b.	**B2** 2nd attempt:	___ ___ minutes	___ ___ : ___ ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2
F5a.	**B3 2 hrs** (120 min):	___ **hr** ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1 **(Skip to b)**	2	___ . ___ mL	1 **(Skip to F6a)**	2 **(Skip to F6a)**
b.	**B3** 2nd attempt:	___ **hr** ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2
F6a.	**B4 5 hrs** (300 min):	___ **hr** ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1 **(Skip to b)**	2	___ . ___ mL	1 **(END)**	2 **(END)**
b.	**B4** 2nd attempt:	___ **hr** ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2

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

↓

Complete pre-iohexol infusion (B0) 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 must occur within 3 months of initial visit

→ 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

↓

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
V1A: remove 1 mL of blood and discard waste; draw 1 mL of blood into SST; record time of blood draw on Specimen Collection Form; flush used IV with at least 3 mL normal saline; **CHECK POST-INFUSION VITALS**

↓

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

↓

V1A/V2: Draw 1 mL of blood into SST at 10 mins (B1), 30 mins (B2), 120 mins (B3) and 300 mins (B4) post-infusion.

*Discard initial 1 mL blood waste at each blood draw

*Record the time each blood draw is completed

*Flush after each blood draw with at least 3 mL normal saline

→ 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 20-30 minutes, but no longer than 1 hour → Centrifuge at 1100-1300 g for 10 minutes in swinghead or 15 minutes in fixed angle*

↓

Following packaging and shipping instructions; send urine, blood and copies of completed forms & 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

GENERAL HISTORY (GH)

Chronic Kidney Disease in Children (CKiD)

SECTION A: GENERAL INFORMATION

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

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

A2. CKiD VISIT #: 0 1 a

A3. FORM VERSION: 0 6 / 0 1 / 0 8

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

A5. INTERVIEWER'S INITIALS: ___ ___ ___

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

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

INTRODUCTION TO PARTICIPANT:

Thank you for participating in this study.

The following pages contain questions about the child's family background, birth history, developmental history and family medical history. I am going to ask you a series of questions. 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.

If at any point in the interview you want me to stop, let me know. As with all study information, your responses will be kept strictly confidential, and the responses you provide will in no way affect your child's clinical care. The first set of questions asks about you and your child's background. If you have trouble understanding anything I say, stop me and I will re-read the question.

Are you ready to begin?

Chronic Kidney Disease in Children

SECTION B: INFORMATION ABOUT YOU

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

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

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

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

SECTION C: CHILD'S BACKGROUND

The next questions are about the child's background.

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

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

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

Male……..	1	
Female……..	2	

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

Yes……..	1	**(Skip to C4)**
No……..	2	

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

Yes……..	1	**(Skip to C4)**
No……..	2	

b. In what country was he or she born?

_____

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

___ ___ ___ ___ (Year)

Don't Know…….. -8

C4. Is (*name of child*) 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
Don't Know.....	-8

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

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

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

SECTION D: CHILD'S BIRTH

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

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

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

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

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

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

___ . ___ kg

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

___ ___ ___ 1= inches 2= cm

Don't Know..... -8

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

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

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

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

Deleted D5.

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

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

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

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

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

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

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

___ ___ 1 = months
2 = weeks
3 = days
-8 = don't know

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

___ ___ 1 = months
2 = weeks
3 = days
-8 = don't know

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

___ ___ years

Don't Know..... -8

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

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

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

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

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

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

___ ___ years

Don't Know..... -8

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

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

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

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

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

SECTION E: CHILD'S EDUCATION

The following questions are about the child's education. Specifically, the next question asks about the highest grade the child has completed. For example, if the child is currently in the 12th grade, then enter "11", or if the child is currently in the 6th grade, then enter "5". In addition, if the child is in the 1st grade, kindergarten or not yet in school, then enter "0".

E1. What is the **highest** grade that (*name of child*) has COMPLETED?

___ ___Grade

Don't Know..... -8

E2. Does (*name of child*) attend school outside of the home?

Yes..... 1

No..... 2 → **(Skip to F1)**

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

___ ___ Days

Don't Know..... -8

E4. Does (*name of child*) have an individualized educational plan? (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

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

Yes..... 1

No..... 2

Don't Know..... -8

SECTION F: CHILD'S FAMILY AND PRIMARY HOUSEHOLD

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

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

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

The following questions ask about the child's primary household. The primary household is the home in which the child lives at least half of the time.

F2. How many days per week does (*name of child*) live in the primary household? Indicate a number between 4 and 7.

____ days

Don't Know..... -8

F3. How many adults live in the primary household? Include **all persons at least 18 years of age**, including siblings and non-relatives.

___ ___ adults

Don't Know..... -8

F4. Which of the following adults (18 years or older) live in the primary household? **(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.	Other.....	1	2	-8

F5. How many people under the age of 18 (including this child), live in the primary household (at least half the time)? Include **all persons under the age of 18**, including siblings and non-relatives.

___ ___ people

Don't Know..... -8

F6. Do any of the people that live in the primary household (at least half the time) routinely smoke cigarettes, cigars, cigarillos or little cigars?

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

The following questions are about the education level of the child's parents in the primary household. Remember, primary household is defined as the home in which the child lives at least half of the time.

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

___ ___ Years

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

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

___ ___ Years

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

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

F9. Please estimate the total income (before taxes) of all members of the **primary household**. Include **total income from wages, business, or investments** for all members of (*name of child*) 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**

SECTION G: CHILD'S FAMILY HISTORY

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

Some people who lost their parents at an early age, or who were adopted, may not have information on their birth family. If you are familiar with the health history of any of the members of the child's biological or birth family, please answer the following questions about these relatives' health to the extent that you are able. If you are uncertain of the answer to any question, please select "Don't Know." If you have trouble understanding anything I say, stop me and I will re-read the question.

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

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

G2. How many **full** siblings does (*name of child*) have? (Full siblings are defined as brothers and sisters, who have the same birth mother and birth father as the child. Include deceased siblings.)

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

Don't Know **……..** -8 → **(Skip to G5)**

G3. How many **living** full siblings does (*name of child*) have?

___ ___ full (living) siblings

Don't Know **……..** -8 → **(Skip to G5)**

GENERAL HISTORY (GH)

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

START GHs1

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

END GHs1

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

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

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

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

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

GENERAL HISTORY (GH)

Next, I am going to ask you some more questions about (*name of child*) biological family members.

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

Yes..... 1

No..... 2 → **(Skip to G7)**

Don't know..... -8 → **(Skip to G7)**

b. Which biological family members? Yes No

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

1. Mother..... 1 2
2. Father..... 1 2
3. Sibling (full brother or sister)... 1 2
4. Grandparents..... 1 2
5. Aunts/Uncles..... 1 2
6. Cousins..... 1 2

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

Yes..... 1

No..... 2 → **(Skip to G8)**

Don't know..... -8 → **(Skip to G8)**

b. Which biological family members? Yes No

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

1. Mother..... 1 2
2. Father..... 1 2
3. Sibling (full brother or sister)... 1 2
4. Grandparents..... 1 2
5. Aunts/Uncles..... 1 2
6. Cousins..... 1 2

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

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

1. High Blood Pressure or Hypertension

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

	Yes	No	Don't Know
Mother.....	1	2	-8
Father.....	1	2	-8
Sibling (full brother or sister).....	1	2	-8
Grandparents.....	1	2	-8
Aunts/Uncles.....	1	2	-8
Cousins.....	1	2	-8

2. High Cholesterol

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

	Yes	No	Don't Know
Mother.....	1	2	-8
Father.....	1	2	-8
Sibling (full brother or sister).....	1	2	-8
Grandparents.....	1	2	-8
Aunts/Uncles.....	1	2	-8
Cousins.....	1	2	-8

3. Diabetes (high blood sugar or sugar diabetes)

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

	Yes	No	Don't Know
Mother.....	1	2	-8
Father.....	1	2	-8
Sibling (full brother or sister).....	1	2	-8
Grandparents.....	1	2	-8
Aunts/Uncles.....	1	2	-8
Cousins.....	1	2	-8

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

4. Stroke before the age of 50

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

	Yes	No	Don't Know
Mother.....	1	2	-8
Father.....	1	2	-8
Sibling (full brother or sister).....	1	2	-8
Grandparents.....	1	2	-8
Aunts/Uncles.....	1	2	-8
Cousins.....	1	2	-8

5. Heart Attack before the age of 50

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

	Yes	No	Don't Know
Mother.....	1	2	-8
Father.....	1	2	-8
Sibling (full brother or sister).....	1	2	-8
Grandparents.....	1	2	-8
Aunts/Uncles.....	1	2	-8
Cousins.....	1	2	-8

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

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

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

c. At what age was treatment started?

1. Mother			___ ___ yrs	
Yes.....	1		Don't Know.....	-8
No.....	2	→ **(skip to 2)**		
Don't Know.....	-8			
2. Father			___ ___ yrs	
Yes.....	1		Don't Know.....	-8
No.....	2	→ **(skip to 3)**		
Don't Know.....	-8			
3. Sibling (full brother or sister)			___ ___ yrs	
Yes.....	1		Don't Know.....	-8
No.....	2	→ **(skip to 4)**		
Don't Know.....	-8			
4.Grandparents			___ ___ yrs	
Yes.....	1		Don't Know.....	-8
No.....	2	→ **(skip to 5)**		
Don't Know.....	-8			
5. Aunts/Uncles			___ ___ yrs	
Yes.....	1		Don't Know.....	-8
No.....	2	→ **(skip to 6)**		
Don't Know.....	-8			
6. Cousins			___ ___ yrs	
Yes.....	1		Don't Know.....	-8
No.....	2	→ **(skip to G10)**		
Don't Know.....	-8			

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

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

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

c. At what age was transplant performed?

1. Mother			___ ___ yrs
Yes.....	1		Don't Know..... -8
No.....	2	→ **(skip to 2)**	
Don't Know.....	-8		
2. Father			___ ___ yrs
Yes.....	1		Don't Know..... -8
No.....	2	→ **(skip to 3)**	
Don't Know.....	-8		
3. Sibling (full brother or sister)			___ ___ yrs
Yes.....	1		Don't Know..... -8
No.....	2	→ **(skip to 4)**	
Don't Know.....	-8		
4.Grandparents			___ ___ yrs
Yes.....	1		Don't Know..... -8
No.....	2	→ **(skip to 5)**	
Don't Know.....	-8		
5. Aunts/Uncles			___ ___ yrs
Yes.....	1		Don't Know..... -8
No.....	2	→ **(skip to 6)**	
Don't Know.....	-8		
6. Cousins			___ ___ yrs
Yes.....	1		Don't Know..... -8
No.....	2	→ **(skip to G11)**	
Don't Know.....	-8		

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

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

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

___ feet ___ ___ inches

Don't Know..... -8

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

___ ___ ___ lbs

Don't Know..... -8

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

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

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

___ feet ___ ___ inches

Don't Know..... -8

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

___ ___ ___ lbs

Don't Know..... -8

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

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

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

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

SOME OF THE FOLLOWING QUESTIONS MAY BE EMBARASSING TO THE CHILD. ASK THIS SECTION OF QUESTIONS WHEN THE CHILD IS NOT IN THE ROOM.

SECTION H: CHILD'S DEVELOPMENTAL HISTORY

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

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

		Age		Don't Know
a.	Turn over.....	___ ___	months	-8
b.	Sit alone.....	___ ___	months	-8
c.	Crawl.....	___ ___	months	-8
d.	Stand alone.....	___ ___	months	-8
e.	Walk alone.....	___ ___	months	-8
f.	Walk upstairs.....	___ ___	months	-8
g.	Walk downstairs.....	___ ___	months	-8
h.	Show interest in or attraction to sound (i.e., showed interest in shaking keys).....	___ ___	months	-8
i.	Understand first words.....	___ ___	months	-8
j.	Speak first words.....	___ ___	months	-8
k.	Speak in sentences (3 or more words).....	___ ___	months	-8

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

Yes..... 1 → **(Skip to H2c)**

No..... 2

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

Yes..... 1 → **(Skip to H3)**

No..... 2

Don't Know..... -8 → **(Skip to H3)**

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

Yes..... 1

No..... 2 → **(Skip to H3)**

Don't Know..... -8 → **(Skip to H3)**

d. How old was (*name of child*) 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 = years
2 = months
3 = weeks
4 = days

Don't Know..... -8

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

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

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

b. How old was (*name of child*) 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 = years
2 = months
3 = weeks
4 = days

Don't Know..... -8

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

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

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

a. Is *(name of child)* wet during the day?

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

b. Is *(name of child)* wet during the night?

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

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

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

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

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

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

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

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

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

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

___ ___ years

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

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

i. Does bed-wetting still occur?

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

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

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

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

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

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

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

i. Does bed-soiling still occur?

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

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

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

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

H6. Has (*name of child*) 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.....	1	2	-8
f.	Unclear speech.....	1	2	-8
g.	Sleep problem.....	1	2	-8
h.	Colic.....	1	2	-8

H7. Which hand does (*name of child*) primarily use to write?

Primarily right..... 1
Primarily left..... 2

H8. Is (*name of child*) 4 years of age or older?

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

H9. During (*name of child*) first 4 years, were any problems noted in the areas listed below?
(Circle "Yes", "No" or "Don't Know" for EACH of the following.)

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

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, DRUG USE AND PHYSICAL ACTIVITY (F02)

Chronic Kidney Disease in Children (CKiD)

SECTION A: GENERAL INFORMATION

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

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

A2. CKiD STUDY VISIT #: 0 1 a

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

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

A5. **TIME MODULE BEGAN:** |__|__| : |__|__| AM..... 1
PM..... 2

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

INTRODUCTION TO PARTICIPANT:

Thank you for participating in this study.

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

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

SMOKING, ALCOHOL, DRUG USE AND PHYSICIAL ACTIVITY (F02)

SECTION B: CIGARETTE USE

The following are some personal questions about your cigarette use. Please <u>circle the number</u> that best matches your answer.

B1. Have you ever smoked a whole cigarette, cigar, cigarillo or little cigar?

Yes..... 1

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

a. How old were you when you smoked a whole cigarette, cigar, cigarillo or little cigar for the first time?

___ ___ years of age

B2. Do you currently smoke cigarettes, cigars, cigarillos or little cigars?

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 C1)

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

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

SECTION D: DRUG USE

The following are personal questions about your use of street drugs to get high. Street drugs include marijuana, inhalants (i.e., glue, paint or aerosol spray cans) and ecstasy. Remember your answers will be kept private.

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

Yes..... 1

No..... 2 **(Skip to E1)**

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

___ ___ ___ times

D3. 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

D4. During your life, how many times have you used ecstasy (also called MDMA)?

___ ___ ___ times

SMOKING, ALCOHOL, DRUG USE AND PHYSICIAL ACTIVITY (F02)

SECTION E: PHYSICAL ACTIVITY

The next questions ask about your physical activity.

E1. On how many of the past 7 days did you exercise or participate in physical activity for **at least 20 minutes that made you sweat and breathe hard**, such as basketball, soccer, running, swimming laps, fast bicycling, fast dancing, or similar aerobic activities?

____ ____ days

E2. On how many of the past 7 days did you participate in physical activity for **at least 30 minutes** that **did not** make you sweat and breathe hard, such as basketball, soccer, running, swimming laps, fast bicycling, fast dancing, or similar aerobic activities?

____ ____ days

E3. During the past 7 days, on how many days were you physically active for a total of **at least 60 minutes per day**? (Add up all the time you spend in any kind of physical activity that increases your heart rate and makes you breathe hard some of the time.)

____ ____ days

E4. On an average school day, how many hours do you watch TV?

I do not watch TV on an average school day.....	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

E5. On an average school day, how many hours do you play videogames and/or use the computer?

I do not play video games and/or use a computer an average school day.....	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

SMOKING, ALCOHOL, DRUG USE AND PHYSICIAL ACTIVITY (F02)

E6. In an average week when you are in school, on how many days do you go to physical education (PE) classes?

____ ____ days **(If "0", Skip to E8)**

E7. During an average physical education (PE) class, how many minutes do you 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

E8. During the past 12 months, on how many sports teams did you play? (Include any teams run by your school or community groups.)

____ ____ teams

F1. **TIME MODULE ENDED: |__|__| : |__|__|** AM..... 1
PM..... 2

THANK YOU FOR YOUR TIME AND EFFORT.

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 6

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

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

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

Instructions: Thinking back on the ***last month***, indicate the number of days in which your child 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

CENTRAL LABORATORY
Intact Parathyroid Hormone (iPTH) and Wide Range C-Reactive Protein (wrCRP)
FORM L08

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 1 / 0 1 / 0 6

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 & wrCRP Results:**

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

b. Wide range C-Reactive Protein (wr CRP) |___||___| . |___| |___| (mg/L)

c. Was serum sample shipped at room temperature? |___|

Yes..……..1
No...……..0

CENTRAL LABORATORY – CYSTATIN C RESULTS

FORM L11

Chronic Kidney Disease in Children (CKiD)

SECTION A: GENERAL INFORMATION

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

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

A2. CKiD VISIT #: ___ ___

A3. FORM VERSION: 0 3 / 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

B3. Which laboratory analyzed the sample?

CBL..... 1
CMH..... 2
Both..... 3

B4. Serum Cystatin C – CBL |___| |___| . |___| |___| (mg/L)

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

B5a. CMH Cystatin Volume |___| |___| . |___| |___|

CENTRAL LABORATORY – IRON TESTS

FORM L12

Chronic Kidney Disease in Children (CKiD)

SECTION A: GENERAL INFORMATION

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

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

A2. CKiD VISIT #: ____ ____

A3. FORM VERSION: 0 7 / 0 1 / 0 8

ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.

SECTION B

B1. ARE TEST RESULTS AVAILABLE?

Yes ..... 1 **(B2)**
No, Sample Inadequate..... 2 **(END)**
No, Other Reason 3

_____ **(END)**
(SPECIFY)

B2. DATE SAMPLE DRAWN:

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

CENTRAL LABORATORY – IRON TESTS

FORM L12

B3. **Iron Results**

a.	Serum Iron	|___|___|___|	(ug/dL)
b.	Total Iron-Binding Capacity (TIBC)	|___|___|___|	(ug/dL)
c.	Tranferrin Saturation (TSAT)	|___|___|	(%)
d.	Ferritin	|___|___|___|	(ng/dL)
e.	Transferrin	|___|___|___|	(mg/dL)

CENTRAL LABORATORY – VITAMIN D

FORM L13

Chronic Kidney Disease in Children (CKiD)

SECTION A: GENERAL INFORMATION

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

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

A2. CKiD VISIT #: ____ ____

A3. FORM VERSION: 1 0 / 1 5 / 0 9

ANY MISSING OR INCOMPLETE TEST RESULTS MUST BE EXPLAINED ON THIS FORM.

SECTION B

B1. ARE TEST RESULTS AVAILABLE?

Yes ..... 1 **(B2)**
No, Sample Inadequate..... 2 **(END)**
No, Other Reason 3

_____ **(END)**
(SPECIFY)

B2. DATE SAMPLE DRAWN:

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

CENTRAL LABORATORY – VITAMIN D

FORM L13

B3. **Vitamin D 25 Hyrdoxy Results**

a. 25-OH Vitamin D2 |___|___|___| (ng/mL)

b. 25-OH Vitamin D3 |___|___|___| (ng/mL)

c. 25-OH Vitamin Total |___|___|___| (ng/mL)

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: 0 9 / 0 1 / 0 9

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. Has the child taken any medications in the last 30 days?
Yes..... 1 **(Skip to B1a)**
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
No..... 2 **(END FORM HERE)**

SECTION B: Inventory

***Instructions:** The CKiD study is interested in obtaining information about **ALL medications**. Complete a MEDS form for each of the medications the child has taken **in the last 30 days prior** to the study visit.

DO NOT LEAVE ANY FIELD BLANK *(unless instructed to do so by skip patterns)*.

B1a. Medication: _____

B1b. Drug Code: ____ ____ ____ _____ ____ **[If DRUG is not listed on the alphabetical coding sheet and a drug code can not be assigned using the classification list, use drug code "999999"]**

B1c. How is (DRUG) taken?

oral.....	1	injection		otic (to ear).....	15
Nasogastric tube.....	6	intravenous.....	5	opthalmologic (to eye).....	16
G-tube/button.....	14	subcutaneous injection.....	8	Other.....	98
per rectal.....	7	intramuscular injection.....	12	Please Specify Other:	
inhalation.....	3	Intradermal injection.....	13	_____	
intranasal.....	4	transdermal	10		
sublingual.....	9	topical.....	11		

B1d. What is the DRUG's form?

Pill/Tablet/Patch/Powder....	1 (Skip to **B2**)	Inhaler/Spray...	3 (Skip to **B1e**)	Liquid (syrup/gel/cream/lotion/injections)...	5 (Skip to **B1e**)
Drop.....	2	Nebulizer.....	4 (Skip to **B1e**)	Rectal Formulation.....	6 (Skip to **B1e**)

B1d1. If drops, where is dose delivered?
Right .....1 Left .....2 Both .....3 Other.....99

Chronic Kidney Disease in Children

MEDICATION AND SUPPLEMENT INVENTORY (MEDS)

Medication Name: _____

B1e. Provide the **volume** of the dose (or number of drops/puffs/nebulizer treatments/suppository) the child takes and **circle the units**: ___ ___ ___. ___ ___

(1 tsp=5mL; 1tbsp=15mL; 1oz=30mL)

mL/cc.....	1	puff/nebulizer....	4	N/A (topical creams).....	-1
L.....	2	suppository.....	5	Other.....	99
drop.....	3	grams.....	6	Please Specify Other:	_____

B1f. Provide the **concentration** of the medication. ___ ___ ___. ___ ___ ___ / ___ ___ ___

This is a **measurement unit** per a **specific volume**. (Refer to medication label.)

Indicate the measuring unit in the first column and the volume unit in the second column.

mcg.....	1	mL or cc.....	1 (Skip to **B5**)
mg.....	2	L.....	2 (Skip to **B5**)
g.....	3	gm.....	3 (Skip to **B5**)
%.....	4	per actuation (spray/puff).....	4 (Skip to **B5**)
units.....	5	N/A (topical cream).....	-1 (Skip to **B5**)
Other.....	99	Other.....	99
Specify:_____		Specify:_____	(Skip to **B5**)

B2. Individual dose (DRUG): **____ ____ ____ ____.____ ____**

B3. Units of (DRUG)

mg.....	1	g.....	10	Other.....	98
mcg.....	2	%.....	11	Specify Other: _____	
vitamins.....	9				

B5. What is the frequency in which (name of child) is supposed to take (DRUG)?

q4 (every 4 hours).....	1	qod (every other day).....	6	q3week (every 3 weeks)...	12
q6 (every 6 hours or 4 times/day).....	2	triweek (3 times/week).....	10	qmonth (every month).....	13
q8 / tid (every 8 hours or 3 times/day)....	3	biweek (2 times/week).....	14	PRN (as needed).....	9
q12 / bid (every 12 hours or twice/day).....	4	qweek (every week).....	7	Other.....	8
q24 / qday (every day or once/day).....	5	q2week (every 2 weeks)....	11	Specify Other: _____	

B6. Is (DRUG) a prescribed medication?

Yes.....1

No..... 2 **(END FORM HERE)**

B7. How many times did (name of child) take prescribed (DRUG) **in the last 30 days**? **____ ____ ____**

B8. Has (name of child) missed taking (DRUG) as prescribed **in the past 30 days**?

Yes.....	1	
No.....	2	→ **(END FORM HERE)**
N/A.....	99	

B9. Has (DRUG) been taken as prescribed **in the past 7 days**?

Yes.....	1	→ **(DO NOT COMPLETE SECTION C)**
No.....	2	
N/A.....	99	→ **(DO NOT COMPLETE SECTION C)**

Chronic Kidney Disease in Children

Medication Name: _____

Section C: Medication Adherence for Prescribed Medication

C1. **In the past 7 days,** how many times did (name of child) take the (DRUG)? ____ ____

C2. **In the past 7 days,** how many times did (name of child) miss taking (DRUG) as prescribed? ____ ____ **(If "0", skip to C3)**

a. For the times when (name of child) missed taking (DRUG), how many times was this due to (name of child) refusing to take this medication? ____ ____

C3. Does (DRUG) bother (name of child)?

Never.....	1	Often.....	3
Sometimes.....	2	Always.....	4

C4. How well do you think (DRUG) helps (name of child)?

Very well.....	1	Not at all.....	3
Somewhat.....	2	Don't Know.....	-8

C5. Please answer the following questions by responding "never", "sometimes" or "a lot" for **EACH** statement. Remember your answers will be kept private.

		Never	Sometimes	A lot
a.	The medication causes side effects.	0	1	2
b.	It is hard to remember to give (name of child) 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 child) 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

C6. Who completed the medication adherence questions (i.e., questions C1-C5)?

Child/young adult	1	Both (Parent and Child/young adult).....	3
Parent.....	2		

Chronic Kidney Disease in Children

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 6 / 0 1 / 0 8

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

A5. INTERVIEWER'S INITIALS: ___ ___ ___

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:

Now, I am going to ask you questions about your child's health history. I will be asking you a series of questions about the current and past diseases that your child 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.

If at any point in the interview you want me to stop, let me know. Finally, I need to re-emphasize that all your answers are confidential, and the responses you provide will in no way affect your child's clinical care. The first set of questions asks about your child's kidney disease. Throughout the questionnaire, I am going to use the words "health care provider" to mean any doctor, nurse, physician assistant or nurse practitioner the child has ever seen. If you have trouble understanding anything I say, stop me and I will re-read the question.

SECTION B: KIDNEY DISEASE

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

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

After Pregnancy..... 2

Don't Know..... -8

B3. How old was (*name of child*) 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 child*) 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 child)* been seen by a Urologist (adult or pediatric)?

Yes..... 1

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

a. How old was (*name of child*) 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 child)* 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 child*) 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 child*) 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 child*) 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 child*) 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, other than kidney disease, that your child may currently have or that your child has had since birth.

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

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. Hypertension (High blood pressure)	1	2 **(Skip to b)**	-8 **(Skip to b)**
i. If hypertensive, what is the status? Continued problem…… 1 Resolved problem……..... 2 Controlled with medication…… 3			
b. Heart Failure (Congestive heart failure)	1	2	-8
c. Stroke	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. INFECTIOUS DISEASE			
a. Hepatitis	1	2 **(Skip to C5b)**	-8 **(Skip to C5b)**
1. If yes, has a doctor or any other healthcare professional ever told you that (name of child) has had any of the following types of hepatitis?			
i. Type A	1	2	-8
ii. Type B	1	2	-8
iii. Type C	1	2	-8
iv. Other Type(s)	1	2 **(Skip to C5b)**	-8 **(Skip to C5b)**

Specify:_____

b.	Other Infection(s)	1	2 **(Skip to C6)**	-8 **(Skip to C6)**

Specify:_____

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

		Yes	No	Don't Know
C6.	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 C7)**	-8 **(Skip to C7)**

Specify:_____

		Yes	No	Don't Know
C7.	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	1	2	-8
o.	Coma or loss of consciousness	1	2	-8

Please indicate whether (*name of child*) 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
C8.	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
C9.	HEARING			
	a. Ear Infections	1	2	-8
	b. Hearing Problems	1	2	-8
	c. Ear Tubes	1	2	-8
C10.	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 your child may currently have or that your child 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 child) has had any broken bones?	1	2 **(Skip to E1)**	-8 **(Skip to E1)**

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

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

SECTION E: NUTRITIONAL ASSESSMENT

The next set of questions asks about your child's appetite 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 or button (GT) is a tube that directly enters the stomach.

E1. During the past week, how would you rate (*name of child*) appetite? Please circle one choice.

Very Good..... 1
Good..... 2
Fair..... 3
Poor..... 4
Very Poor..... 5

E2. Does (*name of child*) use a gastrostomy tube/button or Nasogastric tube (NG tube) for nutritional purposes?

Yes..... 1
No..... 2 **(Skip to E3)**
Don't Know..... -8 **(Skip to E3)**

a. In the past 12 months, how many months has the gastrostomy tube/button or NG tube been used?

___ ___ months

Don't Know..... -8

E3. In a 24 hour time period, does (*name of child*) take any nutritional supplement either by mouth, bottle or feeding tube?

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

Please use the following table to record the type and amount of any nutritional supplement or formula (to increase calories, protein or other nutrient intake) the child usually takes in a <u>24 hour period of time</u>. This should include supplement or formula taken by mouth, bottle or feeding tube.

START MHs1

	a) Name of Formula or Supplement (Ex: Similac PM 60/40, Enfamil LIPIL, Suplena, PediaSure, Nepro, Ensure)	Amount of Formula (For pre-made liquid, use cans or ounces; if made from powder, use teaspoons, tablespoons or cups)		d) Additional ingredients/amounts* (Ex: 2 teaspoons Polycose, 1 Tablespoon MCT oil, 2 scoops Beneprotein) *If there are no additional ingredients/amount, record "N/A"
		b) Amount	c) Unit	
E4.		____ ____	Tsp……..1 Tbsp……..2 Oz……..3 cup ……..4	
E5.		____ ____	Tsp……..1 Tbsp……..2 Oz……..3 cup ……..4	

END MHs1

SECTION F: HEALTHCARE UTILIZATION

Now, I am going to ask you about all the places your child may have received care in the last year.

F1. During the past 12 months, where has (*name of child*) gone to receive medical care? **(Please circle "Yes" or "No" for EACH of the following places.)**

Did (name of child) go to…

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

Now I am going to ask you some questions about your child's use of health care. In this set of questions, I am going to use the words "health care provider" to mean any doctor, nurse practitioner, or physician's assistant you may go to for medical care.

F2. During the past 12 months, how many times did (*name of child*) 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 child) was hospitalized overnight.

___ ___ times

Don't Know..... -8

F3. During the past 12 months, when you or (*name of child*) 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. During the past 12 months, has (*name of child*) 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 child*) hospitalized during the past year?

___ ___ times

Don't Know ..... -8

Now, I am going to ask you some questions about care or social services that your child may have received in the last year.

F5. During the past 12 months, has (*name of child*) been seen by a social worker or a case manager to help him/her obtain services?

Yes 1

No 2

F6. During the past 12 months, has (*name of child*) received care or services from a psychologist, psychiatrist, psychiatric nurse, counselor, or other mental health professional?

Yes 1

No 2

F7. During the past 12 months, has an agency assisted (*name of child*) with food, such as food stamps or WIC, meals on wheels, food pantries, or arranged to have groceries delivered to the child's primary household (i.e., the home in which the child lives at least half the time)?

Yes 1

No 2

F8. During the past 12 months, has a social service agency helped you or (*name of child*) find a place to live?

Yes 1

No 2

F9. During the past 12 months, has (*name of child*) received care from a dentist or dental hygienist?

Yes 1
No 2

F10. During the past 12 months, has (*name of child*) seen a nutritionist or a dietician?

Yes 1
No 2

SECTION G: HEALTH INSURANCE

Now I am going to ask you questions about your child's health care coverage.

G1. Does (*name of child*) 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
No ..... 2 **(Skip to G14)**

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

Chronic Kidney Disease in Children

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

Yes 1
No 2

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

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 6 / 0 1 / 0 8

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

A5. EXAMINER'S INITIALS: ___ ___ ___

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

A7. Is this a V1a or V1b study visit?
Yes..... 1
No..... 2 **(Skip to B1)**

A8. Has consent form been signed by parent or legal guardian?
Yes..... 1
No..... 2 **(STOP*)**

***WRITTEN CONSENT MUST BE OBTAINED before performing any study related procedures or tasks.**

A9. Date parent or legal guardian signed consent form: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A10. Is documented assent required at your institution?
Yes..... 1
No..... 2 **(Skip to A12)**
N/A..... -1 **(Skip to A12)**

A11. Date of child assent: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

A12. Has consent for genetic testing been obtained?
Yes..... 1
No..... 2

A13. Has consent to store biological specimen(s) been obtained?
Yes..... 1
No..... 2

SECTIONS B – G can be completed by a Nurse or other Health Care Provider with CKiD Training

SECTION B: VITAL SIGNS

B1. a. Temperature: ___ ___ ___ . ___ 1 = °C 2 = °F

b. How was the temperature measured? **(Please circle the type of measurement.)**
Oral..... 1
Axillary..... 2
Tympanic..... 3

PHYSICAL EXAMINATION (PE)

DO NOT CALCULATE HEART RATE. ONLY ENTER NUMBER OF BEATS PER MINUTE

B2. Pulse Measurement

a. Number of Heart Beats per minute: ___ ___ ___

B3. Local Clinical Blood Pressure (i.e. Dinamap): ___ ___ ___ / ___ ___ ___

B4. Respiratory Rate

a. Respirations per minute: ___ ___

SECTION C: WEIGHT

C1. Child Weight **(If weight is measured in pounds (lbs), please convert to kilograms (kg).)**
1 lb = (1/2.2) kg **Example: 150 lbs** = 150/2.2 = 68.18 = **68.2 kg**

a. First Measurement: ___ ___ ___ . ___ **(kg)**

b. Second Measurement: ___ ___ ___ . ___ **(kg)**

i. Do the first and second measurements differ by more than 0.2 Kg?

Yes**…….** 1
No**…….** 2 **(Complete Specimen Collection Form)**

ii. Third Measurement: ___ ___ ___ . ___ **(kg)**

SECTION D: HEIGHT/WAIST and HIP CIRCUMFERENCES

D1. Child Length/Height

a. Device used to obtain length/height **(Please circle the device used.)**

Measuring table with firm block and moveable footboard**….** 1
Wall mounted stadiometer**……** 2

b. First Measurement: ___ ___ ___ . ___ (cm)

c. Second Measurement: ___ ___ ___ . ___ (cm)

i. Do the first and second measurements differ by more than 0.3 cm?

Yes**……** 1
No**……** 2 **(Skip to D2)**

ii. Third Measurement: ___ ___ ___ . ___ (cm)

D2. 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 D3)**
No 2
Don't know..... -8

f. Is the biological father present during the study visit?
Yes..... 1
No ..... 3 **(Skip to D3)**

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 D3)**

ii. Father's Third Measurement: ___ ___ ___ . ___ (cm)

D3. Child Waist Circumference

a. First Measurement: ___ ___ ___ . ___ (cm)

b. Second Measurement: ___ ___ ___ . ___ (cm)

i. Do the first and second measurements differ by more than 0.1 cm?
Yes..... 1
No..... 2 **(Skip to D4)**

ii. Third Measurement: ___ ___ ___ . ___ (cm)

D4. Child Hip Circumference

a. First Measurement: ___ ___ ___ . ___ (cm)

b. Second Measurement: ___ ___ ___ . ___ (cm)

i. Do the first and second measurements differ by more than 0.1 cm?
Yes..... 1
No..... 2 **(Skip to E1)**

ii. Third Measurement: ___ ___ ___ . ___ (cm)

SECTION E: BLOOD PRESSURE USING MABIS-MEDIC-KIT ANEROID

E1. Mid Arm Circumference

a. First Measurement: ___ ___ . ___(cm)

b. Second Measurement: ___ ___ . ___(cm)

i. Do the first and second measurements differ by more than 0.2 cm?

Yes..... 1

No..... 2 **(Skip to E2)**

ii. Third Measurement: ___ ___ . ___(cm)

USE THE MID-ARM CIRCUMFERENCE MEASUREMENTS TO SELECT THE APPROPRIATE BP CUFF.

E2. a. Cuff size used **(Please circle the cuff size used.)**

Infant (9.0 to 14.0 cm)..... 1

Child (>14.0 to 21.0 cm)..... 2

Adult (>21.0 cm to 29.0 cm) 3

Large Adult (>29.0 cm to 40.0 cm) 4

Thigh (>40.0 to 52.0cm) 5

- **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

WAIT AT LEAST 30 SECONDS BETWEEN MEASUREMENTS.
AFTER FIRST AND SECOND BLOOD PRESSURE READING, RAISE CHILD'S ARM FOR 15 SECONDS (MAKE SURE THE CHILD IS NOT SUPPORTING THE ARM AT ALL.)

In some patients, the disappearance of sound, i.e. the fifth Korotkoff sound (K5), never occurs and beats can be heard during the entire deflation period. In these circumstances, the fourth Korotkoff sound (K4) should be used to determine the diastolic blood pressure. The fourth Korotkoff sound at the point during deflation where the quality of the sound changes dramatically (e.g. the quality of the beats become muffled.)

e. Second Blood Pressure Reading: ___ ___ ___ / ___ ___ ___ ☐ 1) K4 ☐ 2) K5

f. Third Blood Pressure Reading: ___ ___ ___ / ___ ___ ___ ☐ 1) K4 ☐ 2) K5

g. Initials of Blood Pressure Reader: ___ ___ ___

PHYSICAL EXAMINATION (PE)

SECTION F: HEAD CIRCUMFERENCE

F1. Is the child less than 3 years old?

Yes..... 1

No..... 2 **(Skip to G1)**

F2. Head Circumference

a. First Measurement: ___ ___ ___(cm)

b. Second Measurement: ___ ___ ___(cm)

i. Do the first and second measurements differ by more than .3 cm?

Yes..... 1

No..... 2 **(Skip to G1)**

ii. Third Measurement: ___ ___ ___(cm)

SECTION G: EDEMA

G1. Edema..... ___

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

G2. Is this a Visit 1b study visit?

Yes..... 1 **(Skip to Section I)**

No..... 2

SECTION H should be completed by a Pediatrician, Nurse Practitioner, or Physician Assistant

SECTION H: TANNER STAGING

H1. What is the participant's gender?

Male..... 1 **(Skip to H4)**

Female..... 2

USE THE ASSESSMENT OF PUBERTAL STAGE LAMINATED CARD AND PICTURES TO ANSWER THE FOLLOWING QUESTIONS

H2. If female participant, what is the developmental stage of her pubic hair?

Pre-pubertal..... 1

Sparse growth of slightly pigmented hair..... 2

Darker, coarser, beginning to curl and spread over the symphysis..... 3

Hair has adult characteristics but not adult distribution..... 4

Adult..... 5

H3. If female participant, what is the developmental stage of her breasts?

(Stage 1) Pre-pubertal..... 1 **(Skip to I1)**

(Stage 2) Budding..... 2 **(Skip to I1)**

(Stage 3) Small adult breasts..... 3 **(Skip to I1)**

(Stage 4) Areola and papilla form secondary mound..... 4 **(Skip to I1)**

(Stage 5) Adult breasts..... 5 **(Skip to I1)**

H4. If male participant, what is the developmental stage of his testes and scrotum?

Pre-pubertal	1
Enlargement of testes, scrotal reddening	2
Increasing length more than width of penis, further scrotal enlargement	3
Further penile enlargement, darkening of scrotal skin	4
Adult	5

H5. If male participant, what is the developmental stage of his pubic hair?

Pre-pubertal	1
Sparse growth of slightly pigmented hair	2
Darker, coarser, beginning to curl and spread over the symphysis	3
Hair has adult characteristics but not adult distribution	4
Adult	5

USE THE ORCHIDOMETER (THE GREEN BEADS) PROVIDED BY CKiD.

H6. If male participant, what is the testicular size per the orchidometer?

Bead 1, 2 or 3	1
Bead 4	2
Bead 5	3
Bead 6	4
Bead 8	5
Bead 10	6
Bead 12	7
Bead 15	8
Bead 20	9
Bead 25	10

PHYSICAL EXAMINATION (PE)

SECTION I: PROBLEMS

I1. Were there any sections of the physical exam form that were difficult to complete or not completed (i.e., participant was irritable and/or crying during blood pressure measurement and therefore, unable to obtain 1 of the 3 blood pressure measurements)?

Yes…… 1

No…… 2 **(END HERE)**

I2. Please indicate the section of the physical exam form that was difficult to obtain data or not completed. Please circle yes or no to each section.

	Yes	No	
a. **Section B:** Vital Signs……	1	2	(**skip to b**)
i. Please specify:_____			
b. **Section C:** Weight……	1	2	(**skip to c**)
i. Please specify:_____			
c. **Section D:** Height……	1	2	(**skip to d**)
i. Please specify:_____			
d. **Section E:** Blood Pressure Measure using Mabis Medic Kit……	1	2	(**skip to e**)
i. Please specify:_____			
e. **Section F:** Head Circumference for children less than 3 years old	1	2 **(skip to f)**	N/A (**skip to f**)
i. Please specify:_____			
f. **Section G:** Edema……	1	2	(**skip to g**)
i. Please specify:_____			
g. **Section H:** Tanner Staging……	1	2	(**END HERE**)
i. Please specify:_____			

Chronic Kidney Disease in Children