CKiD Chronic Kidney Disease in Children Cohort Study SECTION A: GENERAL INFORMATION

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

			- -
A2.	CKID VISIT #:		
A3.	FORM VERSION	ON:	<u>1</u> <u>1</u> / <u>0</u> <u>1</u> / <u>1</u> <u>0</u>
A4.	A4. SPECIMEN COLLECTION DATE:		$\frac{1}{M} \frac{1}{M} \frac{1}{D} \frac{1}{D} \frac{1}{Y} \frac{1}{Y} \frac{1}{Y} \frac{1}{Y}$
A5.	FORM COMPL	LETED BY (INITIALS):	
A6.	Is this study vis (accelerated) v	•	Yes 1 No 2
Th	e following sam	nples should be collect	ed.
	mples: rum	Shipped to CBL	Shipped: IMMEDIATELY
Se		<u> </u>	<u> </u>
Se Se	rum	CBL	IMMEDIATELY Batched
Se Se Wh	rum	CBL	IMMEDIATELY Batched (Ship in Jan, Apr, Jul or Oct)
Se Se Wh	rum rum nole Blood nexol Blood	CBL CBL	IMMEDIATELY Batched (Ship in Jan, Apr, Jul or Oct) IMMEDIATELY
Se Se Wh loh Uri	rum rum nole Blood nexol Blood ne	CBL CBL CBL CBL CBL	IMMEDIATELY Batched (Ship in Jan, Apr, Jul or Oct) IMMEDIATELY IMMEDIATELY
Se Se Wh loh Uri	rum rum nole Blood nexol Blood ne	CBL CBL CBL CBL CBL	IMMEDIATELY Batched (Ship in Jan, Apr, Jul or Oct) IMMEDIATELY IMMEDIATELY IMMEDIATELY IMMEDIATELY

Plasma (Biological) NIDDK Biosample Repository Batched

(Ship in Jul, Apr, Jul or Nov)

Urine (Biological) NIDDK Biosample Repository Batched

(Ship in Jul, Apr, Jul or Nov)

Toenail Clippings NIDDK Biosample Repository IMMEDIATELY

(Biological)

A1.



SECTION B: PREGNANCY TEST AND FIRST MORNING URINE COLLECTION

B1.	ls p	participant a female of child-bearing	cipant a female of child-bearing potential?				
		S	,				
_	ROMPT: QUESTION B2 IS FOR FEMALE PARTICIPANTS OF CHILD-BEARING POTENTIAL ONLY. RINE PREGNANCY TEST DATE MUST FALL WITHIN 72 HOURS BEFORE GFR TESTING DATE.						
B2.	a.	Urine pregnancy test date:	$\overline{M} \overline{M} \overline{D} \overline{D} \overline{D} \overline{Y} \overline{Y} \overline{Y} \overline{Y}$				
	b.	Urine pregnancy results:					
		Positive	1 (END; COMPLETE DISENROLLMENT FORM)				
		Negative	2				

FIRST MORNING URINE COLLECTION

Obtain urine collected at home in the specimen container that was shipped to the family before the visit. IF URINE WAS NOT collected at home, collect FRESH urine into a specimen container provided by central biochemistry laboratory (containers were shipped in batches to each site).

The CBL and Heavy Metal urine samples MUST be aliquoted from the same void.

(Refer to MOP Section 11, Communication Memo #126 and/or CBL flowchart for additional information and directions)

First, pour at least10 mL of urine into the CBL transport tube.



Next, pour the remaining volume of urine into the Heavy Metal Study transport tube. If there is no urine left over after aliquoting the CBL sample, then skip the collection of urine for Heavy Metal Study.



Check that all information is correct on the urine collection tube and follow packaging instructions and ship to CBL.

Reasons Code List*: 1= Not required 3 = Participant Refused 5 = Inadvertently Destroyed 7=Insufficient Volume 2 = Difficult Urine Collection 4 = Collection Contamination 6 = Oversight

Sample Type (Required Volume):		(a) Sample Obtained:		(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:		
		Yes	<u>No</u>	OLE GODE LIGIT ABOVE			
B3.	Urine Creatinine, Urine Protein, Urine Albumin (CBL) (10.0 mL-14.5 mL)	1 (skip to c→)	2	(skip to B4)	i. Is this a first morning urine sample? Yes		
B4.	Urine (Heavy Metals) (5.0-14.5 mL)	1 (skip to c→)	2	(skip to C1)	i. Was the same void used to collect both the CBL and Heavy Metal urine samples?		

SECTION C: PRE-IOHEXOL INFUSION BLOOD DRAW

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 Pre-Iohexol Infusion blood draw according to MOP instructions/flowchart below. 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 on pre-iohexol infusion blood draw can be decreased by 1 ml.

For Initial Blood Draw with <u>Syringe</u>, <u>Vacutainer</u> OR <u>Butterfly</u> Method: Select the Type of Consent Obtained (options 1 through 2) That Pertains to the CKiD Participant:

If participant consented to BIOLOGICAL samples:

Collect 20.5-23.0 mL if participant is < 30 kg OR 24.5-27.0 mL if participant is $\ge 30 \text{ kg}$.

If < 30 kg, immediately transfer (using 18 gauge needle) or draw:

- 12.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR
- 3 mL into (1) PST for NIDDK Biosample Repository
- 1 mL into Tan-Top tube for heavy metals
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 3 mL in appropriate tube (not provided) for local Renal Panel
- 2.5 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)

If ≥ 30 kg, immediately transfer (using 18 gauge needle) or draw:

- 14.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR
- 5 mL into (2) PST for NIDDK Biosample Repository
- 1 mL into Tan-Top tube for heavy metals
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 3 mL in appropriate tube (not provided) for local Renal Panel
- 2.5 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)

2 If participant did NOT consent to BIOLOGICAL samples:

Collect 14.5-17.0 mL from all participants (regardless of weight) as specified below.

Immediately transfer (using 18 gauge needle) or draw:

- 9.5 mL into (2) Tiger-Top SSTs for CBL
- 1 mL into Tan-Top tube for heavy metals
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 3 mL in another tube (not provided) for local Renal Panel
- 2.5 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)

PROCESSING OF PRE-IOHEXOL INFUSION BLOOD FOR CBL & NIDDK BR

Invert the SST 5 times & PST 8-10 times gently to mix. Stand SST upright to allow clotting at room temperature for 30 mins and not more than 1 hour (60 mins). Centrifuge SST & PST at MAX SPEED between 1100-1300 g (3000rpm with 10cm radius rotor) for 10 minutes in swinghead units **OR** 15 minutes in fixed angle units (balance tube in centrifuge).*If incomplete separation, centrifuge again for 10-15 minutes. If sample is moderately, slightly or NOT HEMOLYZED, proceed with CBL and NIDDK BR preparation. If sample is GROSSLY HEMOLYZED. You must send hemolyzed **Cystatin C** sample to CBL for Iohexol **CBL Studies NIDDK BR** B0Using the disposable pipette, pipette Blank (B0) and studies. If Using the disposable pipette, Pipette 1.5 mL (<30kg) or 2.5 mL (\ge 30kg) Using the disposable 0.5 mL of serum into Blue Screw-Top child has eaten, aliquot pipette, pipette 0.5 mL of pipette 3.75 mL of serum into of serum into clear top cryovial & 1.5 Cryovial for Cystatin C. hemolyzed sample for serum into Clear-Top with Clear-Top with Red Ring (<30kg) or 2.5 mL(≥ 30 kg) of plasma into Store sample in freezer at -70°C or fasting lipid profile and Red Ring Transport Tube Transport Tube labeled cryovial into green cap insert (use different lower, batch up to 20 samples and send to CBL. Also, if the labeled "B0" for Iohexol "Serum CBL" for pipettes for serum and plasma). ship on dry ice every four months to sample is **GROSSLY** Blank (B0) sample. Follow CBLrenal/iron/uric acid and *If there is any extra serum and/or plasma, the CBL. When shipper is needed, HEMOLYZED (Dark packaging instructions and lipid. Follow packaging then pipette the extra serum into the clear complete "CBL Dry Ice Shipper Red), collect 2.5 mL of ship to CBL with instructions and ship to CBL top cryovial marked "SERUM (Extra)" Request Form" on the CKiD website: additional blood at B1 or accompanying forms, with accompanying forms, and the extra plasma in green cap insert http://www.statepi.jhsph.edu/ckid/admin/ **B2.** Centrifuge and then iohexol blood draws, TAN-Iohexol blood draws, TANcryovial marked "PLASMA (Extra)." Then, follow packaging instructions transfer serum into the TOP blood tube, and urine. TOP blood tube, and urine. No Store samples in freezer at -70°C or lower, and ship to CBL with accompanying extra Clear-Top with Red No FRIDAY shipments. FRIDAY shipments. & batch up to 40 samples and ship on dry forms. No FRIDAY shipments. Rink Tube provided. Refrigerate specimen and Refrigerate specimen and ship ice in January, April, July or October to the Ship on next business day. on next business day. NIDDK BR. When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/. Then, follow packaging instructions. When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ to notify the appropriate

personnel from the CBL and the NIDDK BR.

\sim 4	^ 		INTELLOCAL DI	\sim	
(:1)	ACTILIAL	PRE-IOHEXOL	INFUSION BL	()()()	DRAW

$1 - \Lambda M$	2 = PM
I = AIVI	Z = PIVI

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

	2 = Diffi	cult Blood Drav	W	4 = Red Blood Cell Contamination 6 = Oversight		
(Re	Sample Type equired 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/Uric Acid 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)	
C3.	Cystatin C (1.0 mL in Tiger Top SST)	1 (skip to c→)	2	(skip to C4a)	Date Frozen: /	
C4a	Local CBC (1.0 mL in Lavender Top tube)	1 (skip to C4b)	2	(skip to C4b)	N/A	
C4b	Local Renal Panel (3.0 mL in Local SST)	1 (skip to C5)	2	(skip to C5)	N/A	
C5.	Serum for Fasting Lipid Panel (1.5 mL in Tiger Top SST)	1 (skip to c→)	2	(skip to C6)	Did the child fast after midnight? Yes	
C6.	Whole blood for Heavy Metals (1.0 mL in Tan-Top tube)	1 (skip to C7)	2	(skip to C7)	N/A	

^{*}If the child did not fast, the lipid results will be invalid and therefore will not be reported on the Nephron Lipid Report.

Sites can obtain results for lab values that have been identified as "KEY VARIABLES". To obtain results, go the CKiD Nephron Website: https://statepiaps.jhsph.edu/nephron/groups/aspproc/, click on "Report Menu" and choose the appropriate lab report (i.e., Selected Renal Panel Lab Variables Report.)

C7.	id the participant consent to have biological samples (i.e., serum, plasma and urine samples) stored at the NIDDK Biosample
	epository?

Yes...... 1

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:		(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
		<u>Yes</u>	<u>No</u>	GEE CODE LIST ABOVE	
C8.	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 C9)	Date Frozen: //
C9.	Plasma for NIDDK Biosample Repository (**3.0 mL of blood in one Green Top or **5.0 mL in two Green Top PSTs)	1 (skip to c→)	2	 (skip to D1)	Date Frozen://

^{**} Collect 3.0 mL of whole blood for children < 30 kg and 5.0 mL for children \ge 30 kg

SECTION D: URINE COLLECTION AND PROCESSING FOR REPOSITORY

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

Pour 60 mL of FRESH urine into blue top urine collection cup with 4 protease inhibitor (PI) 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 PI tablets should be returned to the CBL.)

Invert the urine cup gently 5 - 10 times.

The PI TABLET(s) MUST BE **COMPLETELY** DISSOLVED in the urine.

Once the PI tablets are completely dissolved, pour urine into up to six (6) 10 mL urine centrifuge tubes. (**For each tube:** remove yellow top cap, pour urine into tube and SCREW cap back onto tube.) Place no more than 10 mL in each tube.

- OR – Sites may also substitute with tubes normally used to centrifuge urine at site.

Centrifuge urine tube(s) at MAX SPEED between 1100-1300g (3000rpm with 10cm radius rotor) for 10 mins (swinghead units) **OR** 15 mins (fixed angle units).

Decant (pour off) the supernates (liquid reaction) into up to seven (7) 10 mL urine cryovials. Pour no more than 9 mL of urine into each 10 mL cryovial to allow for expansion.

Check that all information is correct on the urine cryovial, promptly freeze and store sample(s) at -70°C or lower. Batch samples and ship at least quarterly (include maximum of 36 cryovials per shipper). When shipper(s) is needed, complete "NIDDK Shipper Request Form" on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/.

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

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) (b) Sample Obtained: If No, specify reason		If No, specify reason	(c) Additional Requirements:	
D1. Urine for NIDDK Biosample Repository (15.0 - 60.0 mL of urine in specimen container and transferred into collection cup with protease inhibitors)	Yes 1 (skip to c→)	<u>No</u> 2	*SEE CODE LIST ABOVE (skip to E2)	i. Was supernate decanted into urine transport cryovials? Yes1 No2 ii. Date Frozen:	
				M M D D Y Y Y Y	

SECTION E: 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).

E2.	2. Was a 1 st morning urine protein to creatinine ratio assay performed at the clinical site's local laboratory? Yes							
	SECTION F: INFUSION SYRI	NGE WEIGHT						
F1.	SCALE MUST FIRST BE ZEROED BEFORE WEIGHING. REMOVE THE <u>SAME</u> SCALE MUST BE USED TO WEIGH THE SYRINGE <u>PR</u>							
	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.)						
<u>PRI</u>	E AND POST SYRINGE WEIGHT MUST BE OBTAINED	IN ORDER TO CALCULATE CHILD'S GFR.						
	SECTION G: IOHEXOL – Refer to <u>Instructions for Iohexol Infus</u>	on and GFR Blood Draws Flow Chart on Page 12						
>	BEFORE INFUSING 5 mL OF IOHEXOL, SET TIMER = 0. SIMULTANI COMPLETE INFUSION BETWEEN 1 TO 2 MINS LEAVE TIMER RUNNING THROUGHOUT IOHEXOL INFUSION AND S							
G1.	IOHEXOL INFUSION a. INFUSION START TIME: : 1 = A	AM 2 = PM						

- DO NOT DRAW BLOOD FROM THE IV SITE WHERE IOHEXOL WAS INFUSED. ANOTHER IV SITE MUST BE USED.
- > WASTE 1 mL OF BLOOD IF DRAWING FROM A SALINE/HEPARIN LOCK.
- > COLLECT 1 mL OF BLOOD FOR EACH IOHEXOL BLOOD DRAW IN THE PROVIDED SST.
- ➤ RECORDING THE EXACT NUMBER OF MINUTES ON THE TIMER IS MORE IMPORTANT THAN DRAWING THE BLOOD EXACTLY AT 120 & 300 MINUTES AFTER IOHEXOL INFUSION. FOR EXAMPLE, IF BLOOD IS DRAWN AT 133 MINS INSTEAD OF 120 MINS, DOCUMENT BLOOD DRAWN @ 133 MINS.
- > TIME SHOULD BE RECORDED IMMEDIATELY AFTER EACH BLOOD SAMPLE IS OBTAINED (i.e., B1, B2).

POST VITALS SHOULD BE TAKEN 10 MINUTES AFTER INFUSION USING LOCAL BLOOD PRESSURE MEASUREMENT (i.e. DINAMAP)

- If rash develops after lohexol Infusion, consider it a reaction to lohexol 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 lohexol. Consider administration of 1 mg/kg Benadryl IV (maximum dose: 50 mg Benadryl IV). Draw up to 0.1 mL 1:1000 Epinephrine for SQ injection and 2 mg/kg Solumedrol IV for administration as ordered by physician.

	(i) Post Vitals:							
G2a.	Post- infusion blood pressure:							
b.	Post-infusion temperature:	1 = °C 2 = °F						
C.	Post-infusion number of heart beats per minute:							
d.	Post-infusion respirations per minute:							

INVERT TUBE 5-10 TIMES AFTER EACH BLOOD DRAW LET SST TUBE STAND 30 MINUTES (BUT NO LONGER THAN 1 HOUR) CENTRIFUGE AT MAX SPEED BETWEEN 1100-1300g (3000rpm with 10cm radius rotor) for 10 MINUTES IN SWING HEAD OR 15 MINUTES IN FIXED ANGLE (BALANCE TUBES IN CENTRIFUGE)

	ALL TIMES should be documented from the initial infusion time	(i) ACTUAL HOURS/ MINUTES on TIMER	(ii) ONLY if Timer malfunctions, record Clock Time using the same clock used for G1a	(iii) Difficult Blood Draw: Yes No	(iv) Blood Volume Collected (1 mL):	(v Centrifuged at Yes) Clinical Site: No
G3a.	B1 2 hrs (120 min):	hr mins	: 1 = AM 2 = PM	1 (Skip to b) 2	mL	1 (Skip to G4a)	2 (Skip to G4a)
b.	B1 2 nd attempt:	hr mins	: 1 = AM 2 = PM	1 2	mL	1	2
G4a.	B2 5 hrs (300 min):	hr mins	: 1 = AM 2 = PM	1 (Skip to b) 2	mL	1 (Skip to H1)	2 (Skip to H1)
b.	B2 2 nd attempt:	hr mins	: 1 = AM 2 = PM	1 2	mL	1	2

IF FAMILY CONSENTED TO THE COLLECTION OF HAIR AND NAIL SAMPLES AT VISIT 4,
THEN PROCEED TO SECTION H
(SEE QUESTIONS ON PAGE 13)





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 blood draw according to instructions V4: after lipid panel is drawn, subject may resume eating and drinking beverages containing sugar (if desired) Start timer and infuse iohexol over 1-2 minutes If infusion site for iohexol IV or butterfly infiltrates, study MUST BE DISCONTINUED Must wait at least 48 hours to repeat study, and repeat visit should occur within 3 months of initial Flush with 10 mL normal saline to ensure infusion of all of the iohexol: IOHEXOL IV OR BUTTERFLY MAY NOW BE If rash develops, consider it a reaction to iohexol and REMOVED notify PI immediately. Consider administering 1mg/kg Benadryl IV (maximum dose 50mg). If systolic BP decreases > 25 mm Hg, diastolic BP 10 minutes post-infusion decreases > 20 mm Hg or pulse increases > 20 beats per CHECK POST-INFUSION VITALS DO NOT COLLECT BLOOD SAMPLE AT 10 MINUTES 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. 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 COMPLETE ADVERSE EVENT FORM and send to CCC for data entry Draw 1 mL of blood into SST at 120 mins (B1) and 300 mins (B2) post-infusion. If blood draw is difficult with poor volume *Discard initial 1 mL blood waste at each blood draw delivery, repeat draw 5 minutes later; record time on Specimen Collection Form *Record the time each blood draw is completed and tube. If blood draw is impossible, *Flush after each blood draw with at least 3 mL normal saline repeat with new venipuncture. Stand SST upright at room Centrifuge at MAX SPEED between 1100-Following each blood draw: temp for 30 minutes, but 1300 g for 10 minutes in swinghead or 15 gently invert tube 5-10 times no longer than 1 hour minutes in fixed angle* Transfer serum into the cryovial labeled "Iohexol Serum." Following packaging and shipping instructions; send urine, blood and copies of completed shipping form(s) & confirmation of written consent to CBL

Physician should be immediately available (in person or by phone) during Iohexol Infusion Encourage fluids throughout the visit.

*1100-1300 g = 3000 rpm with 10 cm radius rotor



TOENAIL CLIPPINGS FOR THE REPOSITORY SHOULD BE SHIPPED ONLY IF THE SAMPLE <u>WAS NOT</u> COLLECTED AT V4

SECTION H:

H1	a.	Is this a study Visit 4?	Yes	1 (skip to H1c)
			No	2
	b.	Were toenail clippings collected at Visit 4?	Yes	1 (END; if toenail clippings collected at V4 do not collect at V6)
			No	2
	c. Did the participant consent to have biological samples (i.e., nail clippings) stored at NIDDK Biosample Repository's			., nail clippings) stored at NIDDK Biosample Repository?
		Yes	. 1	
		No	. 2 (END)	

TOENAIL CLIPPING COLLECTION

- The collection of TOENAILS is preferred. DO NOT collect fingernail clippings. Also DO NOT collect toenails if participant has nail
 fungus, or discoloration causing pain or discomfort.
- STAINLESS STEEL NAIL CLIPPERS MUST BE USED TO COLLECT NAIL CLIPPINGS. Use small (pediatric size) stainless steel nail clippers (see Figure A) for younger 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) toenails, removing approximately 1 millimeter from each nail (See Figure C). Be prepared to collect flyaway nails.
- ➤ (To use nail clippers, see Figures A D). Refer to CKiD MOP Section 12 for further details.
- Carefully place the nail clippings into the cryovial (see Figure D). After using the nail clipper,
- > spray the clipper with **SaniZide Plus** and wipe with clean cloth.

ALTHOUGH PICTURES DEPICT THE CLIPPING OF FINGERNAILS, AT VISIT 4 TOENAIL CLIPPINGS ARE PREFERRED.

Figure A





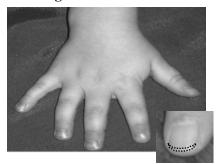


Figure B





Figure C



Provide 10 nail clippings that are at least 1 mm tall

	Yes	1 (END)
	No	2
a.	How many toenail clippings were collected?	
b.	Specify reason "10" toenail clippings were not collected: (e.g.,	, Nail fungus or discoloration causing pain or discomfort
	Nail fungus or discoloration	1 (END)
	Nails not long enough	2 (END)
	Participant Refused	-7 (END)
	Other	3