# 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

A1.

Plasma (Biological)

			-    -
A2.	CKiD VISIT #:		
A3.	FORM VERSION	ON:	0 1 / 0 1 / 1 2
A4.	4. SPECIMEN COLLECTION DATE:		:: <u>M M D D Y Y Y Y</u>
A5.	FORM COMPL	ETED BY (INITI	_S):
A6.	Is this study vis (accelerated) v		Yes
The	e following sam	ples should be	ollected.
	mples:	Shipped to	Shipped:
	rum rum	CBL CBL	IMMEDIATELY Batched (Ship in Jan, Apr, Jul or Oct)
Wh	ole Blood	CBL	IMMEDIATELY
Iohexol Blood CBL		CBL	IMMEDIATELY
Urine CBL		CBL	IMMEDIATELY
If consent is obtained for biological sam			
	mples:		<u>Shipped:</u>
Sei	rum (Biological	) NID	K Biosample Repository Batched

Urine (Biological) NIDDK Biosample Repository Batched

(Ship in Jan, Apr, Jul or Oct)

(Ship in Jan, Apr, Jul or Oct)

**Batched** 

Nail Clippings (Biological) NIDDK Biosample Repository IMMEDIATELY

Hair (Biological) NIDDK Biosample Repository IMMEDIATELY

BATCHED SAMPLES SHOULD BE SHIPPED QUARTERLY (Jan, Apr, July or Oct)
OR MORE OFTEN IF DESIRED BY THE SITE COORDINATOR!

**NIDDK Biosample Repository** 

Samples should NOT be stored for more than one year. For specific questions, contact your CCC prior to shipment.



# SECTION B: PREGNANCY TEST AND FIRST MORNING URINE COLLECTION

Is participant a female of child-bearing potential?

B1.

	- 1	3	
		5	· ·
			PARTICIPANTS OF CHILD-BEARING POTENTIAL ONLY. ALL WITHIN 72 HOURS BEFORE GFR TESTING DATE.
B2.	a.	Urine pregnancy test date:	
	b.	Urine pregnancy results:  Positive  Negative	1 (END; COMPLETE DISENROLLMENT FORM) 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:		
		<u>Yes</u>	<u>No</u>	OLE GODE LIGIT ADOVE			
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 sa ii. Time of Collection::	No2	
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?	Yes1 No2	

#### SECTION C: PRE-IOHEXOL INFUSION BLOOD DRAW

Encourage fluids throughout the visit.

1

Place two IV lines (18-22 gauge polyethylene catheters) using two separate vascular access sites ---OR---

Place one butterfly and one IV line (18-22 gauge polyethylene catheter) using two separate vascular access sites; use tape to stabilize butterfly for iohexol infusion

--OR---

Use butterfly for pre-iohexol and individual blood draw sticks; use tape to stabilize butterfly for Iohexol infusion

Complete Pre-Iohexol Infusion blood draw according to 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 1100-1300g (3000rpm with 10cm radius rotor) for 10 minutes in swinghead units **OR** 15 minutes in fixed angle units (balance tube in centrifuge).\*If incomplete separation, centrifuge again for 10-15 minutes. If sample is 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 **CBL Studies** NIDDK BR Using the disposable pipette, pipette Pipette 1.5  $\overline{mL}$  (<30kg) or 2.5 mL (> Iohexol Blank (B0). If Using the disposable pipette, Using the disposable 0.5 mL of serum into Blue Screwpipette 3.75 mL of serum 30kg) of serum into clear top child has eaten, aliquot pipette, pipette 0.5 mL of Top Cryovial for Cystatin C. cryovial & 1.5 mL (<30kg) or 2.5 into Clear-Top with Red serum into Clear-Top with hemolyzed sample for Store sample in freezer at -70°C or Ring Transport Tube labeled Red Ring Transport Tube mL (> 30kg) of plasma into cryovial fasting lipid profile and lower, batch up to 20 samples and "Serum CBL" for CBL labeled "B0" for Iohexol into green cap insert (use different send to CBL. Also, if the ship on dry ice every four months to Blank (B0) sample. Follow renal/iron chemistries and pipettes for serum and plasma). the CBL. When shipper is needed, sample is **GROSSLY** lipids. Follow packaging \*If there is any extra serum and/or packaging instructions and complete "CBL Dry Ice Shipper **HEMOLYZED** (Dark ship to CBL with instructions and ship to CBL plasma, then pipette the extra serum Request Form" on the CKiD with accompanying forms, Red), collect 2.5 mL of accompanying forms, into the clear top cryovial marked website: iohexol blood draws, TANiohexol blood draws, TAN-"SERUM (Extra)" and the extra additional blood at B1 or http://www.statepi.jhsph.edu/ckid/admin/ TOP blood tube, and urine. plasma in green cap insert cryovial TOP blood tube, and urine. **B2.** Centrifuge and then Then, follow packaging No FRIDAY shipments. marked "PLASMA (Extra)." No FRIDAY shipments. transfer serum into the instructions and ship to CBL with Refrigerate specimen and Store samples in freezer at -70°C or Refrigerate specimen and extra Clear-Top with Red accompanying forms. No ship on next business day. ship on next business day. lower, & batch up to 40 samples and FRIDAY shipments. ■ Ring Tube provided. ship on dry ice in January, April, July Ship on next business day. or October to the NIDDK BR. When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: http://www.statepi.jhsph.edu/ckid/admin/. Then, follow packaging instructions.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: <a href="http://www.statepi.jhsph.edu/ckid/admin/">http://www.statepi.jhsph.edu/ckid/admin/</a> to notify the appropriate personnel from the CBL and the NIDDK BR.

$C_1$	$\Lambda \subset T \cup \Lambda \cup$	TIME OF	PRE-IOHEXOL	INIELICION RI	OOD DDWW
UI.	ACTUAL		PKE-IUHEAUL	. IINFUSIUN DI	_ししし してAVV

1 _ \ \ \ \ \	2 = PM
I = AIVI	$\angle = \Gamma IVI$

#### PROMPT: IF SUSPECTED BLOOD DRAW ADVERSE EVENT (i.e., infection), complete ADVERSE EVENT (ADVR) Form

Reasons Code List<sup>\*</sup>: 1= Not required 3 = Participant Refused 5 = Inadvertently Destroyed
2 = Difficult Blood Draw 4 = Red Blood Cell Contamination 6 = Oversight

	2 = Difficult Blood Draw 4 = Red Blood Cell Contamination 6 = Oversignt								
(Re	Sample Type equired Volume in Top Color Tube Type):	(a) Sample Obta <u>Yes</u>	ined:	(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? Yes1 No2*				
C6.	Whole blood for Heavy Metals (1.0 mL in Tan-Top tube)	1 (skip to C7)	2	(skip to C7)	N/A				

<sup>\*</sup>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: <a href="https://statepiaps.jhsph.edu/nephron/groups/aspproc/">https://statepiaps.jhsph.edu/nephron/groups/aspproc/</a>, click on "Report Menu" and choose the appropriate lab report (i.e., Selected Renal Panel Lab Variables Report.)

C7.	27. Did the participant consent to have biological samples (i.e., serum, plasma and urine samples) stored at the NIDDK Biosam Repository?								
	Yes 1								
	No		2 (Skip to E2)						
	Reasons Code List <sup>*</sup> :	1= Not required 2 - Difficult Blood Draw	3 = Participant Refused 4 = Red Blood Cell Contamination	5 = Inadvertently Destroyed 6 = Oversight					

	Sample Type (Required Volume in Top Color Tube Type):	(a) Sample Obta	ained:	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:	
		<u>Yes</u>	<u>No</u>	SEE 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:  M M D D Y Y Y Y	
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: /	

<sup>\*\*</sup> Collect 3.0 mL of whole blood for children  $\leq$  30 kg and 5.0 mL for children  $\geq$  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 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:

# of Protease
Inhibitor Tablets

10 - 15 mL
16 - 30 mL
2
31 - 45 mL
36 - 60 mL
4

Invert the urine cup gently 5 - 10 times.

The PROTEASE INHIBITOR TABLET(s) MUST BE COMPLETELY DISSOLVED in the urine.

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

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

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

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

Check that all information is correct on the urine cryovials, promptly freeze and store sample(s) at -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: <a href="http://www.statepi.jhsph.edu/ckid/admin/">http://www.statepi.jhsph.edu/ckid/admin/</a>. Then, follow packaging instructions.

When pickup has been scheduled, complete "Online 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 2 = Difficult Urine 3 = Participant 4 = Collection 5 = Inadvertently 6 = Oversight

Collection Refused Contamination Destroyed

Sample Type (Required Volume in Top Color Tube Type):		(a) Sample Obtained: <u>Yes</u> <u>No</u>		(b) If No, specify reason *SEE CODE LIST ABOVE	(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)	1 (skip to c→)	2		i. Was supernate decanted into urine transport cryovials? Yes1 No2

#### 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).

α	2 of the Control of t									
E2.	Was a 1 <sup>st</sup> morning urine protein to creatinine ratio assay performed at the clinical site's local laboratory?  Yes									
	SECTION F: INFUSION SYRINGE WEIGHT									
F1.	F1. SCALE MUST FIRST BE ZEROED BEFORE WEIGHING. REMOVE ALUMINUM FOIL PRIOR TO WEIGHING THE SYRINGE. THE <u>SAME</u> SCALE MUST BE USED TO WEIGH THE SYRINGE <u>PRE AND POST</u> IOHEXOL INFUSION.									
	a. Syringe Weight <b>Pre-lohexol Infusion</b> : (g)									
	b. Syringe Weight <b>Post-Iohexol Infusion</b> : (g) (Post-Infusion Weight should be <b>at least 6.0g</b> less than Pre-Infusion Weight. If Post-Infusion Weight is not at least 6g less, please confirm.)									
<u>PR</u>	E AND POST SYRINGE WEIGHT MUST BE OBTAINED IN ORDER TO CALCULATE CHILD'S GFR.  SECTION G: IOHEXOL – Refer to Instructions for Iohexol Infusion and GFR Blood Draws Flow Chart on Page 12									
>	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									
G1.	IOHEXOL INFUSION  a. INFUSION START TIME: : 1 = AM 2 = PM									

- > DO NOT DRAW BLOOD FROM THE IV SITE WHERE IOHEXOL WAS INFUSED. ANOTHER IV SITE MUST BE USED.
- WASTE 1 mL OF BLOOD IF DRAWING FROM A SALINE/HEPARIN LOCK.
- > 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 <u>AFTER</u> 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)

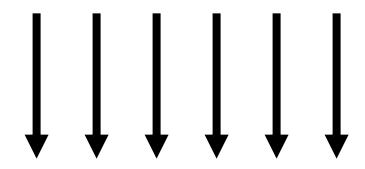
- If rash develops after lohexol Infusion, consider it a reaction to lohexol and notify PI immediately. Consider administration of 1 mg/kg Benadryl IV (maximum dose: 50 mg Benadryl IV).
- In the rare event that systolic BP decreases more than 25 mm Hg, diastolic BP decreases more than 20 mmHg, or pulse 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 Typical range: <b>36.1 – 38.3</b> 2 = °F Typical range: <b>94.5 – 100.6</b>							
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	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		ult Blood Drawn via Draw: Needle Stick		(v) Blood Volume Collected (1 mL):	(vi) Centrifuged at Clinical Site: Yes No	
G3a.	<b>B1 2 hrs</b> (120 min):	hr	mins	: 1 = AM 2 = PM	1 (Skip to b)	2	1	2	mL	1 (Skip to G4a)	2 (Skip to G4a)
b.	<b>B1</b> 2 <sup>nd</sup> attempt:	hr	mins	: 1 = AM 2 = PM	1	2	1	2	mL	1	2
G4a.	<b>B2 5 hrs</b> (300 min):	hr	mins	: 1 = AM 2 = PM	1 (Skip to b)	2	1	2	mL	1 (END FORM)	2 (END FORM)
b.	<b>B2</b> 2 <sup>nd</sup> attempt:	hr	mins	: 1 = AM 2 = PM	1	2	1	2	mL	1	2

IF FAMILY CONSENTED TO THE COLLECTION OF HAIR AND NAIL SAMPLES, BUT THE SAMPLES WERE NOT COLLECTED AT VISIT 1B, 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

--OR---

Use butterfly for pre-iohexol and individual blood draw sticks; use tape to stabilize butterfly for Iohexol infusion

Complete pre-iohexol infusion blood draw according to instructions

Start timer and infuse iohexol over 1-2 minutes

If infusion site for iohexol IV or butterfly infiltrates, study MUST BE DISCONTINUED Must wait at least 48 hours to repeat study, and repeat visit should occur within 3 months of initial

Flush with 10 mL normal saline to ensure infusion of all of the iohexol; IOHEXOL IV OR BUTTERFLY MAY NOW BE REMOVED

10 minutes post-infusion CHECK POST-INFUSION VITALS DO NOT DRAW BLOOD AT 10 MINUTES

Obtain post-infusion weight of syringe on the same scale as prior to infusion. Record weight on the Specimen Collection Form prior to shipment to the CCC

Draw 1 ml of blood into SST at 120 mins (B1), and 300 mins (B2).

\*For IV ONLY: Discard initial 1 mL blood waste at each blood draw

\*For IV ONLY: Flush after each blood draw with at least 3 mL normal saline

\*Record the time each blood draw is completed

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

If blood draw is difficult with poor volume delivery, repeat draw 5 minutes later; record time on Specimen Collection Form and tube. If blood draw is impossible, repeat with new venipuncture.

Following each blood draw: gently invert tube 5-10 times

Stand SST upright at room temp for 30 minutes, but no longer than 1 hour

Centrifuge at MAX SPEED between 1100-1300 g for 10 minutes in swinghead or 15 minutes in fixed angle\*

Transfer serum into the cryovial labeled "Iohexol Serum."

Following packaging and shipping instructions; send urine, blood and copies of completed shipping form(s) & confirmation of written consent to CBL

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

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



# **SECTION H:**

H2.	Were nail clippings and hair samples previously	collected and shipped at V1b?
	Yes	1 (END)
	No	
H3.	Did the participant consent to have biological sai	mples (i.e., nail clippings and hair samples) stored at NIDDK Biosample Repository?
	Yes	1
	No	. 2 <b>(END)</b>
	NAIL	. CLIPPING COLLECTION
	<ul> <li>discoloration causing pain or discomfort. If the the participant's toenails instead. FINGERNA CRYOVIAL (collect one or the other).</li> <li>STAINLESS STEEL NAIL CLIPPERS MUST steel nail clippers (see Figure A) for younger Both sizes are included in the CKiD starter participant of the blades of the nail clippers with Sar prior to use (provided by the CBL).</li> <li>Whenever possible, the Study Coordinator stapproximately 1 millimeter from each nail (See Figures A – D). Ref</li> </ul>	nould clip all (10) fingernails, removing see Figure C). Be prepared to collect flyaway nails. Fer to CKiD MOP Section 12 for further details. Sovial (see Figure D). After using the nail clipper,
Figu	ıre A	Figure B Figure C











Provide 10 nail clippings that are at least 1 mm tall

14. C	Does the participant have acrylic nails?				
		Yes	1 (Skip to H6)		
		No	2		
15. V	5. Were 10 fingernail clippings collected?				
	Yes		1 (Skip to I1)		
			2		
а	а.	How many fingernail clippings were collected?			
b	b. Specify reason "10" fingernail clippings were not collected.				
		Nails not long enough	1 (Skip to H6)		
		Participant Refused	-7 (Skip to H6)		
		Other	2		
		i. Specify:			
6. V			1 (Skip to I1)		
		i. Specify: re 10 toenail clippings collected? Yes	1 (Skip to I1)		
;	Wei	i. Specify: re 10 toenail clippings collected? Yes	1 (Skip to I1) 2		
;	Wei	i. Specify:  re 10 toenail clippings collected? Yes  No How many toenail clippings were collected?  ———— Specify reason "10" toenail clippings were not collected:	1 (Skip to I1) 2		
;	Wei	i. Specify:  re 10 toenail clippings collected?  Yes	1 (Skip to I1) 2 (e.g., Nail fungus or discoloration causing pain or		
;	Wei	i. Specify:  re 10 toenail clippings collected?  Yes	1 (Skip to I1) 2  (e.g., Nail fungus or discoloration causing pain or 1 (Skip to I1)		

#### **SECTION I: HAIR SAMPLE COLLECTION**

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

Figure A



**Occipital Region of Scalp** 

Figure B



Figure C



Place the KID ID label tightly around all 20 strands.

Figure D



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

l1.	Doe	s the participant have permed, dyed, colored, or chemically alte	red hair?
		Yes	1 <b>(END)</b>
		No	2
l2.	Was	the Study Coordinator able to cut at least 20 fibers of hair from	the occipital region?
	Yes		1 <b>(END)</b>
		No	2
	a.	Specify reason "20" hair fibers were not collected:	
		Hair not long enough	1 (END)
		Participant Refused	-7 <b>(END)</b>
		Other	2
		i. Specify:	