## **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				
	-   _  -   _			
CKiD VISIT #:	<u>0</u> <u>3</u>			
FORM VERSION:	<u>0 6 / 0 1 / 0 8a</u>			
SPECIMEN COLLECTION DATE:	$\overline{M} \ \overline{M}' \ \overline{D} \ \overline{D}' \ \overline{Y}' \ \overline{Y}' \ \overline{Y}' \ \overline{Y}'$			
FORM COMPLETED BY: (INITIALS)	<del></del>			
Is this study visit an irregular	Yes 1			
(accelerated) visit?	No 2			
	CKID VISIT #: FORM VERSION:  SPECIMEN COLLECTION DATE:  FORM COMPLETED BY: (INITIALS)			

The following sample should be collected.

be collected:

Samples: Shipped to: Shipped:

Serum CBL **IMMEDIATELY** 

**CBL BATCHED** Serum

(Ship in Jan, Apr, Jul or Oct)

Urine **CBL IMMEDIATELY** \*lohexol Blood **CBL IMMEDIATELY** 

\*ONLY COLLECT IOHEXOL BLOOD IF THIS IS AN ACCELERATED STUDY VISIT.

Please refer to questions 22 on the Eligibility Form to determine if

biological consent was obtained. Depending on the type of consent, the following samples may or may not

Samples: Shipped: Shipped to:

Serum (Biological) **NIDDK Biosample Repository BATCHED** 

(Ship in Jan, Apr, Jul or Oct)

Plasma (Biological) **NIDDK Biosample Repository BATCHED** 

(Ship in Jan, Apr, Jul or Oct)

Urine (Biological) NIDDK Biosample Repository **BATCHED** 

(Ship in Jan, Apr, Jul or Oct)

\*Whole Blood (Genetic) Rutgers Repository

*IMMEDIATELY* 

\*ONLY collect whole blood for Genetic Repository, if sample was not collected at V1b OR if sample collected at V1b was inadequate.

#### SECTION B: PREGNANCY TEST AND FIRST MORNING URINE COLLECTION

D4	1		formale of abild because a	- 12017((D) 11(			
B1	. IS	participant a	female of child-bearing p				
				1 (See PROMPT Be	elow)		
	N	0		2 (Skip to B3)			
	_	•	N B2 IS FOR FEMALE F TEST DATE MUST FA			OTENTIAL ONLY.	
В	2. a.	Urine preg	nancy test date:	//	<u> </u>		
	b.	Urine preg	nancy results:				
		Positive		1 (END; COMPLET	TE DISENROLLMENT	FORM)	
		Negative		2			
			FIRST MOR	RNING URIN	<u>E COLLECTIO</u>	N	
						it. IF URINE WAS NOT collections were shipped in batches to	
						••	
		Dour	10 to 14.5 ml of wine in	eta liaht hlua tan um	ina gallaction tuba (nra	avidad by CDL)	
		Poul	10 to 14.5 mL of urine in	no fight blue top ur	me confection tube (pro	ovided by CBL).	
_				-			<u>—</u>
	Che	ck that all inf	formation is correct on the	e urine collection tu	be and follow packaging	ng instructions and ship to C	CBL.
		*	4 11 4 2 1	0 0 0	D ( )		
	Reaso	ns Code List <sup>*</sup> :	1= Not required	3 = Participant		= Inadvertently Destroyed	
			2 = Difficult Urine Collecti	on 4 = Collection (	Contamination 6	= Oversight	
	(Red		nple Type 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>			

#### **SECTION C: Visit 3 BLOOD DRAW**

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 4): <u>ONLY collect whole blood for Genetic Repository</u>, if sample was not collected at V1b or sample collected at V1b was inadequate.

## If participant consented to both BIOLOGICAL AND GENETIC samples:

Collect 27.3-29.8 mL if participant is < 30 kg OR 31.3-33.8 mL if participant is  $\ge 30 \text{ kg}$ .

#### If $\leq 30$ kg, immediately transfer (using 18 gauge needle) or draw:

 If not collected at V1b - 7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository

#### (ACD Tubes must be COMPLETELY FILLED)

- 12.5 mL into (2) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 3 mL into (1) PST for NIDDK Biosample Repository
- 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)

#### If $\geq 30$ kg, immediately transfer (using 18 gauge needle) or draw:

 If not collected at V1b - 7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository

#### (ACD Tubes must be COMPLETELY FILLED)

- 14.5 mL into (2) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 5 mL into two (2) PSTs for NIDDK Biosample Repository
- 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)

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

Collect 19.5-22.0 mL if participant is < 30 kg OR 23.5-26.0 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 PST for NIDDK Biosample Repository

3

- 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 $\geq$ 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 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 participant consented to GENETIC samples ONLY, collect 21.3 – 23.8 mL from all participants (regardless of weight):

Immediately transfer or draw:

- If not collected at V1b 7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository (ACD Tubes must be COMPLETELY FILLED)
- 9.5 mL into (2) Tiger-Top SST for CBL
- ullet 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)

## If participant did NOT consent to BIOLOGICAL samples and Genetic samples:

Collect 13.5-16.0 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 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)

### **SECTION C: Visit 3 BLOOD DRAW PROCESSING**

**CBL & NIDDK BR (Serum)** 

Invert the Tiger Top SST 5 times gently to mix.

Stand SST upright to allow clotting at room temperature for 30 mins and not more than 1 hour (60 mins).

Vitamin D

mL of serum

into a red-top

cryovial for

Vitamin D

CBL

Pinette 0.5

Centrifuge SST at 1100-1300g for 10 mins in swinghead OR 15 mins in fixed angle. \*If incomplete separation, centrifuge again 10-15 mins.

You must send hemolyzed sample to CBL for. Also if the sample is **GROSSLY HEMOLYZED** (**Dark Red**), then collect 2.5 mL of additional blood in a SST. Centrifuge and then transfer serum into the extra Clear-Top with Red Ring Tube provided.

# CBL Studies

Using the disposable pipette, pipette 3.0 of serum into Clear-Top with red ring Transport Tube labeled "Serum CBL" for CBL renal/iron chemistries). Follow packaging instructions and ship to CBL with accompanying forms and urine. No FRIDAY shipments. Refrigerate specimen and ship on next business day.

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

#### <u>iPTH/wrC</u> <u>RP</u>

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

#### Cystatin C Using the

disposable pipette, pipette 0.5 mL of serum into Blue Screw-Top Cryovial for Cystatin

### NIDDK (Serum)

Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) serum into clear top cryovial for NIDDK BR (use different pipettes for serum and plasma).

\*If there is any extra serum, then pipette the extra serum into the clear top cryovial marked "SERUM (Extra).

Store sample in freezer at -70°C or

lower, batch up to 40 samples and

ship during Jan, Apr, Jul and

Oct. When shipper is needed,

complete "NIDDK BR Shipper

http://www.statepi.jhsph.edu/ckid/admin

Then, follow packaging

instructions.

Request Form" on CKiD website:

Store sample in freezer at -70°C or lower and batch up to 20 samples and ship quarterly during the months of **January**, **April**, **July and October**. When shipper is needed, complete "CBL Dry Ice Shipper Request Form" on the CKiD website: <a href="http://www.statepi.jhsph.edu/ckid/admin/">http://www.statepi.jhsph.edu/ckid/admin/</a> 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 Heather

Higgins, Sandra Ke and Alicia Wentz that sample(s) have been shipped to NIDDK BR.

## **NIDDK BR (Plasma)**

Invert each PST 8-10 times gently to mix.

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

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

Store sample in freezer at -70°C or lower, batch up to 40 samples and ship during the months of **Jan, April, July and Oct**. When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website:

http://www.statepi.jhsph.edu/ckid/admin/ Then, follow packaging instructions.

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

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

### **SECTION C: Visit 3 BLOOD DRAW AND PROCESSING**

C1. 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):		ned:	(b) If No, specify reason	(c) Additional Requirements:
		<u>Yes</u>	<u>No</u>	*SEE CODE LIST ABOVE	
C2.	Renal/Iron Chemistries (6.0 mL in Tiger Top SST)	1 (skip to c→)	2	(skip to C2a)	i. Indicate the appearance of the serum after centrifuging.  Grossly (Dark Red)
C2a.	Cystatin C (1.0 mL in Tiger Top SST)	1 (skip to c→)	2	(skip to C3)	Date Frozen: / /
C3.	Serum for iPTH, wrCRP & Vitamin D (2.5 mL of blood 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

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.)

C5.	Did the participant consent to have biological sam	ples (i.e., serum, plasma and urine) stored at NIDDK Biosample Repository
	Yes	1
	No	2 (Skip to E1)

Reasons Code List\*:1= Not required3 = Participant Refused5 = Inadvertently Destroyed2 = Difficult Blood Draw4 = Red Blood Cell Contamination6 = 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>	CEE CODE LIOT ABOVE				
C6.	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 C7)	Date Frozen:/			
C7.	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 D1)	Date Frozen: /			

<sup>\*\*</sup> Collect 3.0 mL of whole blood for children < 30 kg and 5.0 mL for children ≥ 30 kg

#### SECTION D: Visit 3 URINE COLLECTION AND PROCESSING FOR REPOSITORY

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

Pour 15-60 mL (preferably 60 mL) of FRESH urine into 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
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 -70°C or lower. Batch samples and ship at least quarterly (include maximum of 36 cryovial 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 and Alicia Wentz 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:		(b) If No, specify reason	(c) Additional Requirements:		
` '	. 21 /	<u>Yes</u>	<u>No</u>	*SEE CODE LIST ABOVE			
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	(skip to E1→)	i. Was supernate decanted into urine transport cryovials? Yes1 No2 ii. Date Frozen: / /		

#### SECTION E: WHOLE BLOOD FOR GENETIC REPOSITORY

BLOOD FOR THE GENETIC REPOSITORY SHOULD BE SHIPPED ONLY IF THE SAMPLE <u>WAS NOT</u> COLLECTED AT V1B OR IF THE SAMPLE OBTAINED AT V1B WAS INADEQUATE (i.e, cell lines were not immortalized).

If participant has consented to have blood stored at Rutgers but it is not necessary to collect the blood for the Genetic Repository, Code question E2b as "01."

E1. Did the participant consent to have whole blood stored at Rutgers, the Genetic Repository?

Yes.....

E3. Is this an irregular (accelerated) study visit?

Yes.....

SPECIMEN.

Reasons Code List\*: 1= Not required

	2 = Difficult Blo	ood Draw 4 = Red E	Blood Cell	Contamination 6 = Overs	sight
	Sample Type (Required Volume in Top Color Tube Type):	(a) Sample Obta		(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
E2.	Whole Blood for Rutgers Cell & DNA Repository (7.8 mL of blood in 3 pediatric (2.6 mL) Yellow Top ACD tubes)	Yes 1 (skip to c→)	<u>No</u> 2	(skip to E3)	i. Date of Blood Draw: ///

3 = Participant Refused

5 = Inadvertently Destroyed

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

## ONLY COMPLETE SECTIONS F & G IF THIS IS AN IRREGULAR STUDY VISIT.

For an irregular study visit, additional blood should be collected for lohexol-Based GFR.

#### SECTION F: IRREGULAR STUDY VISIT INFUSION SYRINGE WEIGHT

F1.	SCALE MUST FIRST BE ZEROED BEFORE WEIGHING. REMOVE A THE <u>SAME</u> SCALE MUST BE USED TO WEIGH THE SYRINGE <u>PRE</u>	
	a. Syringe Weight <b>Pre-Iohexol 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.)
PRE	AND POST SYRINGE WEIGHT MUST BE OBTAINED	IN ORDER TO CALCULATE CHILD'S GFR.
	SECTION G: IRREGULAR ST	UDY VISIT
	IOHEXOL – Refer to <u>Instructions for Iohexol Infusion and C</u>	GFR Blood Draws Flow Chart on Page 12
> C	BEFORE INFUSING 5 mL OF IOHEXOL, SET TIMER = 0. SIMULTANED COMPLETE INFUSION BETWEEN 1 TO 2 MINS LEAVE TIMER RUNNING THROUGHOUT IOHEXOL INFUSION AND SU	
<i>/</i> L	LEAVE TIMER ROMAING THROUGHOUT TOHEXOL INFUSION AND SC	BSEQUENT BLOOD DRAWS
G1.	IOHEXOL INFUSION	
	a. INFUSION START TIME: : : 1 = AN	1  2 = PM
> DO	NOT DRAW BLOOD FROM THE IV SITE WHERE IOHEXOL WAS INF	USED. ANOTHER IV SITE MUST BE USED.
> WA	STE 1 mL OF BLOOD IF DRAWING FROM A SALINE/HEPARIN LOCK	<b>(</b>

> TIME SHOULD BE RECORDED IMMEDIATELY <u>AFTER</u> EACH BLOOD SAMPLE IS OBTAINED (i.e., B1, B2, B3, and B4).

> 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

COLLECT 1 mL OF BLOOD FOR EACH IOHEXOL BLOOD DRAW IN THE PROVIDED SST.

MINS INSTEAD OF 30 MINS, DOCUMENT BLOOD DRAWN @ 33 MINS.

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 G1a	(iii) Difficult Blo Draw: Yes	ood No	(iv) Blood Volume Collected (1 mL):	Centrifuged a	v) t Clinical Site: No
G2a.	<b>B1</b> 10 min:	minutes	: 1 = AM 2 = PM	1 (Skip to b)	2	mL	1 (Skip to G3a)	2 (Skip to G3a)
b.	<b>B1</b> 2 <sup>nd</sup> attempt:	minutes	: 1 = AM 2 = PM	1	2	mL	1	2

# INVERT TUBE 5-10 TIMES AFTER EACH BLOOD DRAW LET SST TUBE STAND 20-30 MINUTES (BUT NO LONGER THAN 1 HOUR)

CENTRIFUGE AT 1100-1300g (3000rpm with 10cm radius rotor) for 10 MINUTES IN SWING HEAD OR 15 MINUTES 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 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:						
G3a.	Post- infusion blood pressure:	/					
b.	Post-infusion temperature:	1 = °C					
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	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):	Centrifuged at	v) Clinical Site:
G4a.	<b>B2</b> 30 min:	minutes	: 1 = AM 2 = PM	1 (Skip to b) 2	mL	1 (Skip to G5a)	2 (Skip to G5a)
b.	<b>B2</b> 2 <sup>nd</sup> attempt:	minutes	: 1 = AM 2 = PM	1 2	mL	1	2
G5a.	<b>B3 2 hrs</b> (120 min):	hr mins	: 1 = AM 2 = PM	1 (Skip to b) 2	mL	1 (Skip to G6a)	2 (Skip to G6a)
b.	<b>B3</b> 2 <sup>nd</sup> attempt:	<b>hr</b> mins	: 1 = AM 2 = PM	1 2	mL	1	2
G6a.	<b>B4 5 hrs</b> (300 min):	<b>hr</b> mins	: 1 = AM 2 = PM	1 (Skip to b) 2	mL	1 (END)	2 (END)
b.	<b>B4</b> 2 <sup>nd</sup> attempt:	<b>hr</b> mins	: 1 = AM 2 = PM	1 2	mL	1	2

#### **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

Start timer and infuse johexol 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

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

**V3 Accelerated Visit:** 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

**V3** Accelerated Visit: 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

Following each blood draw:

gently invert tube 5-10 times

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

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.

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

Stand SST upright at room

temp for 20-30 minutes,

but no longer than 1 hour