	•	ase in Children Cohort Study (CKiD) ENERAL INFORMATION
A1.		R ENTER NUMBER IF ID LABEL IS NOT AVAILABLE
		= =
A2.	CKID VISIT #:	<u>0 1 a</u>
A3.	FORM VERSION:	<u>0 3 / 0 1 / 1 8a</u>
A4.	DATE OF VISIT:	$\frac{1}{M} \frac{1}{M} \frac{1}{D} \frac{1}{D} \frac{1}{Y} \frac{1}{Y} \frac{1}{Y} \frac{1}{Y} \frac{1}{Y}$
A5.	FORM COMPLETED BY (INITIALS	S):
The followi	ng samples should be collected.	
<u>Samples:</u>	Shipped to:	Shipped:
Serum	CBL	IMMEDIATELY
Serum	CBL	Batched (Ship in Jan, Apr, Jul or Oct)
Urine	CBL	IMMEDIATELY
Iohexol Blo		IMMEDIATELY
	IOHEXOL BLOOD DRAW: Only Cohorts 1 & 2 participants had p	if Cohort 3 participants who consent to iohexol previous iGFR>90
BA		SHIPPED QUARTERLY (Jan, Apr, July or Oct) IRED BY THE SITE COORDINATOR!
		stored for more than six (6) months. ontact your CCC prior to shipment.
		AND FIRST MORNING URINE COLLECTION
	participant a female of child-bearing po s	
PROMPT: URINE PR	: QUESTION B2 IS FOR FEMALE PA REGNANCY TEST DATE MUST FALL hing iohexol protocol, B2 MUST BE	RTICIPANTS OF CHILD-BEARING POTENTIAL ONLY. WITHIN 72 HOURS BEFORE STUDY VISIT DATE. COMPLETED BEFORE IOHEXOL TESTING IS
B2. a.	Urine pregnancy test date:	///
b.	Urine pregnancy results:	
	Positive 1	(END; COMPLETE TRANSITIONAL (TRS03) FORM)
	Negative 2	
		OTA

9

Chronic Kidney Disease in Children

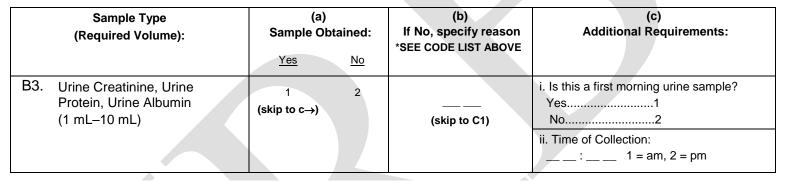
FIRST MORNING URINE COLLECTION

Obtain urine collected at home in the specimen container that was shipped to the family before the visit. If URINE WAS NOT COLLECTED at home, collect FRESH urine sample during CKiD visit.

Pour at least 1 mL of urine into the CBL transport tube.

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

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



SECTION C: Visit 1a BLOOD DRAW (Select the type of consent obtained, option 1 or 2)

If participant is completing study visit, without iohexol protocol: Collect 4.5-5.5 mL from all participants (regardless of weight) 1

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

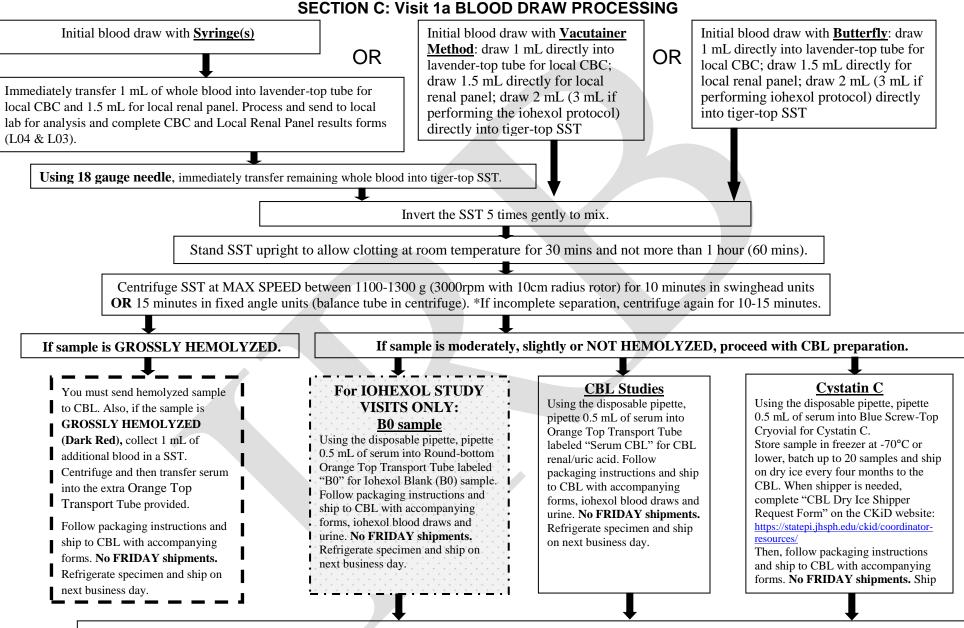
- 2 mL into Tiger-Top SST for CBL
- 1 mL in lavender-top tube for local CBC (tube not provided in CBL kit)
- 1.5 mL in appropriate tube (not provided) for local Renal Panel
- 1 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)

For Participant Completing Iohexol Study Visit:

For IOHEXOL study visits, collect:

• 1mL of additional blood into Tiger Top SST for CBL Iohexol Blank (B0) blood sample

Iohexol is infused at the time of initial blood draw. Refer to page 6 for Instructions for Iohexol Infusion and GFR Blood Draws.



When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: <u>https://statepi.jhsph.edu/ckid/coordinator-resources/</u> to notify appropriate personnel that sample(s) have been shipped to CBL.

C1. ACTUAL TIME OF BLOOD DRAW

____: ___: ____: 1 = AM 2 = PM

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

Reasons Code List [*] :	1= Not required 2 = Difficult Blood Draw	4 = Red Blood Cell Contamination 5 = Inadvertently Destroyed	7 = Exceeds maximum allowable volume
	3 = Participant Refused	6 = Oversight	

(Rec	Sample Type juired Volume in Top Color Tube Type):	(a) Sample Obtaine <u>Yes</u> <u>N</u>	d: <u>lo</u>	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
C2.	Renal/ Uric Acid Chemistries (2.0 mL in Tiger Top SST)	1 (skip to c→)	2	(skip to C3)	Indicate the appearance of the serum after centrifuging. Grossly (Dark Red)1 Moderately (Red/Light Red)2 Slightly (Pink)3 Not Hemolyzed (Yellow)4
C3.	Cystatin C (1.0 mL in Tiger Top SST)	1 2 (skip to c→)	2	 (skip to C4)	Date Frozen: ///
C4.	Local CBC (1.0 mL in Lavender Top tube)	1 2 (skip to C5)	2	(skip to C5)	N/A
C5.	Local Renal Panel (1.5 mL in Local SST)	1 2 (skip to D2)	2	(skip to D2)	N/A
<u>https</u>				s "KEY VARIABLES". To	l o obtain results, go the CKiD Nephron Website: choose the appropriate lab report (i.e., Selected Rena

SECTION D: OPTIONAL TESTS LOCAL LAB TEST (IF CLINICALLY INDICATED)

Check with the PI at your clinical site to determine whether or not it is **CLINICALLY INDICATED** to obtain urine for local lab. These are instances when the PI needs results immediately and/or the participant needs additional local labs performed (i.e., local Urine Creatinine and Urine Protein).

QUESTION D1 HAS BEEN DELETED.

D2. Was a urine protein to creatinine ratio assay performed at the clinical site's local laboratory?

Yes..... 1 No...... 2 → Complete Local Urine Assay Results Form L06 ONLY if local labs are CLINICALLY INDICATED

IOHEXOL PROTOCOL

D3. Is the participant completing iohexol study visit?

Yes, consent obtained..... 1

No..... $2 \rightarrow$ (End Form)

ONLY COMPLETE SECTIONS E & F IF PARTICIPANT IS COMPLETING IOHEXOL STUDY VISIT.

Only Cohort 3 participants who consent to iohexol protocol or Cohorts 1 & 2 participants with previous iGFR>90 should complete iohexol protocol. If you have additional questions, contact CCC. For an iohexol study visit, additional blood (including blood for the lohexol "B0" Blank sample) should be collected for lohexol-Based GFR.

SECTION E: INFUSION SYRINGE WEIGHT

- E1. SCALE MUST BE FIRST 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> IOXEHOL INFUSION.
 - a. Syringe Weight Pre- Iohexol Infusion: _____. (g)
 - b. Syringe Weight Post- Iohexol Infusion: _____.

(Post-Infusion Weight should be **at least 6.0g** less than Pre-Infusion Weight. If Post-Infusion Weight is not at least 6g less, please confirm.)

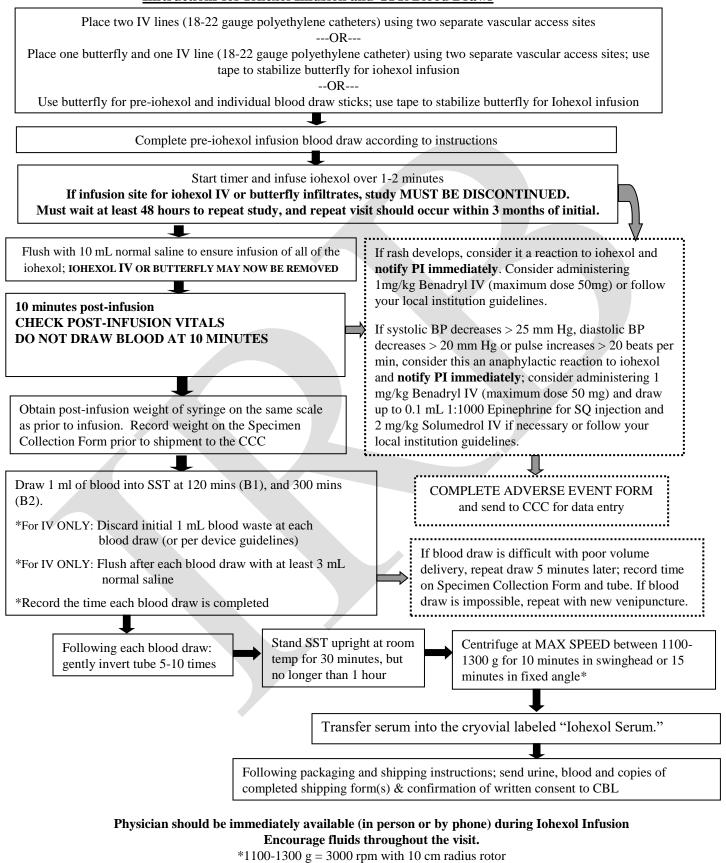
PRE AND POST SYRINGE WEIGHT MUST BE OBTAINED IN ORDER TO CALCULATE PARTICIPANT'S GFR.

(q)

SECTION F: IOHEXOL – Refer to Instructions for Iohexol Infusion and GFR Blood Draws Flow Chart on Page 6

- **BEFORE** INFUSING **5 mL** of IOHEXOL, **SET TIMER = 0**. SIMULTANEOUSLY START TIMER AND BEGIN IOHEXOL INFUSION
- > COMPLETE INFUSION BETWEEN 1 TO 2 MINS.
- LEAVE TIMER RUNNING THROUGHOUT IOHEXOL INFUSION AND SUBSEQUENT BLOOD DRAWS

Instructions for Iohexol Infusion and GFR Blood Draws





SPECIMEN COLLECTION FORM for Visit 1a (L01)

- F1. IOHEXOL INFUSION
 - a. INFUSION START TIME: _____ 1 = AM 2 = PM
- > DO NOT DRAW BLOOD FROM THE IV SITE WHERE IOHEXOL WAS INFUSED. ANOTHER IV SITE MUST BE USED.
- ▶ WASTE 1 mL OF BLOOD IF DRAWING FROM A SALINE/HEPARIN LOCK (OR PER DEVICE GUIDELINES).
- > COLLECT 1 mL OF BLOOD FOR EACH IOHEXOL BLOOD DRAW IN THE PROVIDED SST.
- RECORDING THE EXACT NUMBER OF MINUTES ON THE TIMER IS MORE IMPORTANT THAN DRAWING THE BLOOD EXACTLY AT 120 & 300 MINUTES AFTER IOHEXOL INFUSION. FOR EXAMPLE, IF BLOOD IS DRAWN AT 133 MINS INSTEAD OF 120 MINS, DOCUMENT BLOOD DRAWN @ 133 MINS.
- TIME SHOULD BE RECORDED IMMEDIATELY <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) or follow your local institution guidelines.
- In the rare event that systolic BP decreases more than 25 mm Hg, diastolic BP decreases more than 20 mmHg, or pulse increases more than 20 beats per min, notify PI immediately to evaluate reaction and complete the Adverse Event (ADVR) Form. Consider the possibility of an anaphylactic reaction to 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, or follow your local institution guidelines.

	(i) Post Vitals:	
F2a.	Post- infusion blood pressure:	/
b.	Post-infusion temperature:	 1 = °C Typical range: 36.1 – 38.3 2 = °F Typical range: 94.5 – 100.6
C.	Post-infusion number of heart beats per minute:	
d.	Post-infusion respirations per minute:	

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

	ALL TIMES should be documented from the initial infusion time	(i) ACTUAL HOURS/ MINUTES on TIMER		(ii) ONLY if Timer malfunctions, record Clock Time using the same clock used for G1a	(iii) Difficult Blood Dra Yes		Blood	(iv) Drawn via buncture No	(v) Blood Volume Collected (1 mL):	(v Centri at Clinic Yes	fuged
F3a.	B1 2 hrs (120 min):	hr	mins	: 1 = AM 2 = PM	1 (Skip to b)	2	1	2	mL	1 (Skip to F4a)	2 (Skip to F4a)
b.	B1 2 nd attempt:	hr	mins	1 = AM 2 = PM	1	2	1	2	mL	1	2
F4a.	B2 5 hrs (300 min):	hr	mins	: 1 = AM 2 = PM	1 (Skip to b)	2	1	2	mL	1 (END FORM)	2 (END FORM)
b.	B2 2 nd attempt:	hr	mins	: 1 = AM 2 = PM	1	2	1	2	mL	1	2