

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: 1 1 / 0 1 / 1 0

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

A5. FORM COMPLETED BY:
(INITIALS)

The following samples should be collected.

<u>Samples:</u>	<u>Shipped to:</u>	<u>Shipped:</u>
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)

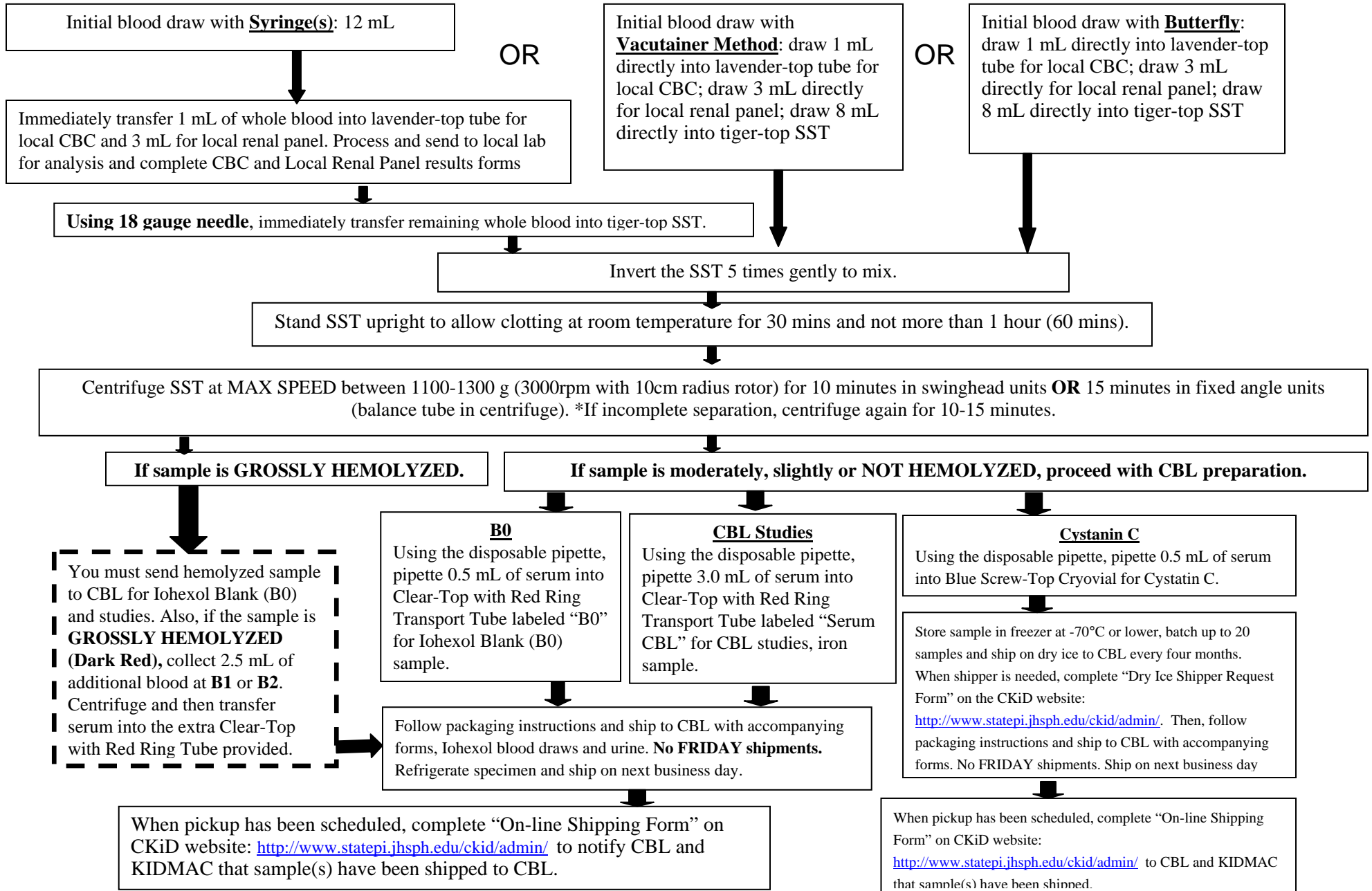
PROMPT: QUESTION B2 IS FOR FEMALE PARTICIPANTS OF CHILD-BEARING POTENTIAL ONLY. URINE PREGNANCY TEST DATE MUST FALL WITHIN 72 HOURS BEFORE GFR TESTING DATE.

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

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SECTION C: PRE-IOHEXOL INFUSION BLOOD DRAW



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C1. ACTUAL TIME OF PRE-IOHEXOL INFUSION 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/Uric Acid Chemistries (7.0 mL in Tiger Top SST)	1 2 (skip to c→)	_____ (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→)	_____ (skip to C4)	Date Frozen: ____ / ____ / ____ M M D D Y Y Y Y
C4. Local CBC (1.0 mL in Lavender Top tube)	1 2 (skip to C5)	_____ (skip to C5)	N/A
C5. Local Renal Panel (3.0 mL in Local SST)	1 2 (skip to D2)	_____ (skip to D2)	N/A

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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

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- 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 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.

(i) Post Vitals:		
F2a.	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:	___ ___

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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 F1a	(iii) Difficult Blood Draw:		(iv) Blood Volume Collected (1 mL):	(v) Centrifuged at Clinical Site:	
				Yes	No		Yes	No
F3a.	B1 2 hrs (120 min):	___ hr ___ mins	___ : ___ 1 = AM 2 = PM	1 (Skip to b)	2	___ . ___ mL	1 (Skip to F4a)	2 (Skip to F4a)
b.	B1 2nd attempt:	___ hr ___ mins	___ : ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2
F4a.	B2 5 hrs (300 min):	___ hr ___ mins	___ : ___ 1 = AM 2 = PM	1 (Skip to b)	2	___ . ___ mL	1 (END FORM)	2 (END FORM)
b.	B2 2nd attempt:	___ hr ___ mins	___ : ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2

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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 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 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
CHECK POST-INFUSION VITALS
DO NOT COLLECT BLOOD SAMPLE 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) 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

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

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.

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