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: 0 1 / 0 1 / 0 6

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

A5. FORM COMPLETED BY: (INITIALS) ___ ___ ___

SECTION B: PREGNANCY TEST AND URINE COLLECTION

B1. Is participant a female of child-bearing potential?

Yes..... 1 **(See PROMPT Below)**

No..... 2 **(Skip to B4)**

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

B3. Is this study visit a Make-Up GFR visit?

Yes..... 1 **(Skip to E1)**

No..... 2

URINE COLLECTION

Obtain urine collected at home. (Family was instructed to collect urine at home in a container, such as a jar. IF URINE WAS NOT collected at home, collect FRESH urine into an initial urine collection cup or hat (provided by the site).

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Pour 5 to 14.5 mL of urine into blue top urine collection tube (provided by CBL).

↓

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
	2 = Difficult Urine Collection	4 = Collection 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:**
B4. 1st Morning Urine (Urine Creatinine, Urine Protein) (5.0 mL–14.5 mL in Blue Top tube)	1 / 2 **(skip to c→)**	__ __ **(skip to C1)**	i. Was urine collected at home? Yes.....1 No.....2
			ii. Time of Collection: __ __ : __ __ 1 = am, 2 = pm

Encourage fluids throughout the visit.

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Place two IV lines (22 gauge polyethylene catheters); one in each arm
--OR---
Place one butterfly and one IV line (22 gauge polyethylene catheter); one in each arm; use tape to stabilize butterfly for Iohexol infusion

↓

Complete Time=0 (Pre-Iohexol Infusion) blood draw according to MOP instructions/flowchart on page 3. 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 can be decreased by 1 ml.

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SECTION C: PRE-IOHEXOL INFUSION (B0) BLOOD DRAW

Initial blood draw with **Syringe**: 10 mL if local BMP is clinically indicated, 7 mL if not. *A baseline Iohexol level will be run with the BMP, so be sure to draw BMP pre-iohexol

Immediately transfer 1 mL of whole blood into lavender-top tube for local CBC and 3 mL for local BMP (**if clinically indicated**). Process and send to local lab for analysis and complete CBC and Local BMP results forms (L04 & L03).

Using 18 gauge needle, immediately transfer remaining whole blood into tiger-top SST.

OR

Initial blood draw with **Vacutainer Method**: draw 1 mL directly into lavender-top tube for local CBC; draw 3 mL directly for local BMP (**if clinically indicated**); draw 6 mL directly into tiger-top SST

OR

Initial blood draw with **Butterfly**: draw 1 mL directly into lavender-top tube for local CBC; draw 3 mL directly for local BMP (**if clinically indicated**); draw 6 mL directly into tiger-top SST

Invert the SST 5-10 times gently to mix.

Stand SST upright to allow clotting at room temperature for 30 mins.

Centrifuge SST at MAX SPEED (between 1100-1300 g) 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 GROSSLY HEMOLYZED.

If the sample is **GROSSLY HEMOLYZED (Dark Red),** pipette 2.5 mL of serum into Clear-Top Transport Tube labeled "B0/SST" and send to CBL. If a BMP was NOT collected, then collect 2.5 mL of additional blood at **B1**, **B2**, **B3** or **B4**. Then transfer 2.5 mL into the extra Clear-Top Tube provided.

Follow packaging instructions and ship to CBL with accompanying forms, Iohexol blood draws and urine. **No FRIDAY shipments.** Refrigerate specimen and ship on next business day.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/ to notify Paula Maier and Alicia Wentz that sample(s) have been shipped to CBL.

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

Using the disposable pipette, pipette 2.5 mL of serum into Clear-Top Transport Tube labeled "B0/SST" for CBL chemistries and HPLC Creatinine.

Using the disposable pipette, pipette 0.5 mL of serum into Blue Screw-Top Cryovial for Cystatin C.

Store sample in freezer at -70°C or lower, batch up to 20 samples and ship on dry ice every four months to Children's Mercy Hospital. When shipper is needed, complete "Cystatin C 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 Nancy Wilson and Alicia Wentz that sample(s) have been shipped to CMH.

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C1. ACTUAL TIME OF PRE-IOHEXOL INFUSION (B0) 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 Chemistries and HPLC (5.0 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 (Clear).....4
C3. Cystatin C (1.0 mL in Tiger Top SST)	1 **(skip to c→)** 2	___ ___ **(skip to C4)**	Frozen Date: ___ ___ /___ ___ /___ ___ ___ ___ M M D D Y Y Y Y
C4. Local CBC (1.0 mL in Lavender Top tube)	1 **(skip to C5)** 2	___ ___ **(skip to C5)**	**N/A**

C5. Please indicate:

a. The fax number to which the Central Biochemistry Lab should fax lab results

Fax number: _____

b. The recipient's name who will be receiving the results

Recipient's name: _____

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

Check with the PI at your clinical site to determine whether or not it is **CLINICALLY INDICATED** to obtain additional local labs. These are instances when the PI can not wait for faxed CBL lab results (2-3 working days) or the participant needs additional local labs performed (i.e., local BMP, local Urine Creatinine and Urine Protein) OR CBL sample is GROSSLY HEMOLYZED.

D1. Was a basic metabolic panel (BMP) assay performed at the clinical site's local laboratory?

Yes..... 1 → **Complete Local Basic Metabolic Panel Results Form L03 ONLY if local labs are CLINICALLY INDICATED or CBL Renal Panel Serum is GROSSLY HEMOLYZED**

No..... 2

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 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.**
- **COLLECT 1 mL of BLOOD FOR EACH IOHEXOL BLOOD DRAW AND TRANSFER INTO THE PROVIDED SST.**
- **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 MINS INSTEAD OF 30 MINS, DOCUMENT BLOOD DRAWN @ 33 MINS.**
- **TIME SHOULD BE RECORDED IMMEDIATELY AFTER EACH BLOOD SAMPLE IS OBTAINED (i.e., B1, B2, B3, B4).**

		(i) **ACTUAL MINUTES on TIMER**	(ii) **ONLY** if Timer malfunctions, record Clock Time using the same clock used for F1a	(iii) **Difficult Blood Draw:** **Yes**	**No**	(iv) **Blood Volume Collected (1 mL):**	(v) **Centrifuged at Clinical Site:** **Yes**	**No**
F2a.	**B1** 10 min:	___ ___ minutes	___ ___ : ___ ___ 1 = AM 2 = PM	1 **(Skip to b)**	2	___ . ___ mL	1 **(Skip to F3a)**	2 **(Skip to F3a)**
b.	**B1** 2nd attempt:	___ ___ minutes	___ ___ : ___ ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2

INVERT TUBE 5-10 TMES AFTER EACH BLOOD DRAW

LET SST TUBE STAND 20-30 MINUTES (BUT NO LONGER THAN 1 HOUR)

CENTRIFUGE FOR AT LEAST 15 MINUTES AT 3000 RPM

POST VITALS SHOULD BE TAKEN IMMEDIATELY AFTER THE 10 MINUTE BLOOD DRAW 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.**

SPECIMEN COLLECTION FORM for Visit 1a (L01)

(i) Post Vitals:		
F3a.	Post- infusion blood pressure:	___ ___ ___ / ___ ___ ___
b.	Post-infusion temperature:	___ ___ . ___ 1 = ºC 2 = ºF
c.	Post-infusion number of heart beats per minute:	___ ___ ___
d.	Post-infusion respirations per minute:	_____

		(i) ACTUAL MINUTES ON TIMER	(ii) **ONLY** if Timer malfunctions, record Clock Time using the same clock used for F1a	**(iii) Difficult Blood Draw:** **Yes**	**No**	**(iv) Blood Volume Collected (1 mL):**	**(v) Centrifuged at Clinical Site:** **Yes**	**No**
F4a.	**B2** 30 min:	___ ___ minutes	___ ___ : ___ ___ 1 = AM 2 = PM	1 **(Skip to b)**	2	___ . ___ mL	1 **(Skip to F5a)**	2 **(Skip to F5a)**
b.	**B2** 2nd attempt:	___ ___ minutes	___ ___ : ___ ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2
F5a.	**B3** 120 min (2 hrs):	___ hr ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1 **(Skip to b)**	2	___ . ___ mL	1 **(Skip to F6a)**	2 **(Skip to F6a)**
b.	**B3** 2nd attempt:	___ hr ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2
F6a.	**B4** 300 min (5 hrs):	___ hr ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1 **(Skip to b)**	2	___ . ___ mL	1 **(END)**	2 **(END)**
b.	**B4** 2nd attempt:	___ hr ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2

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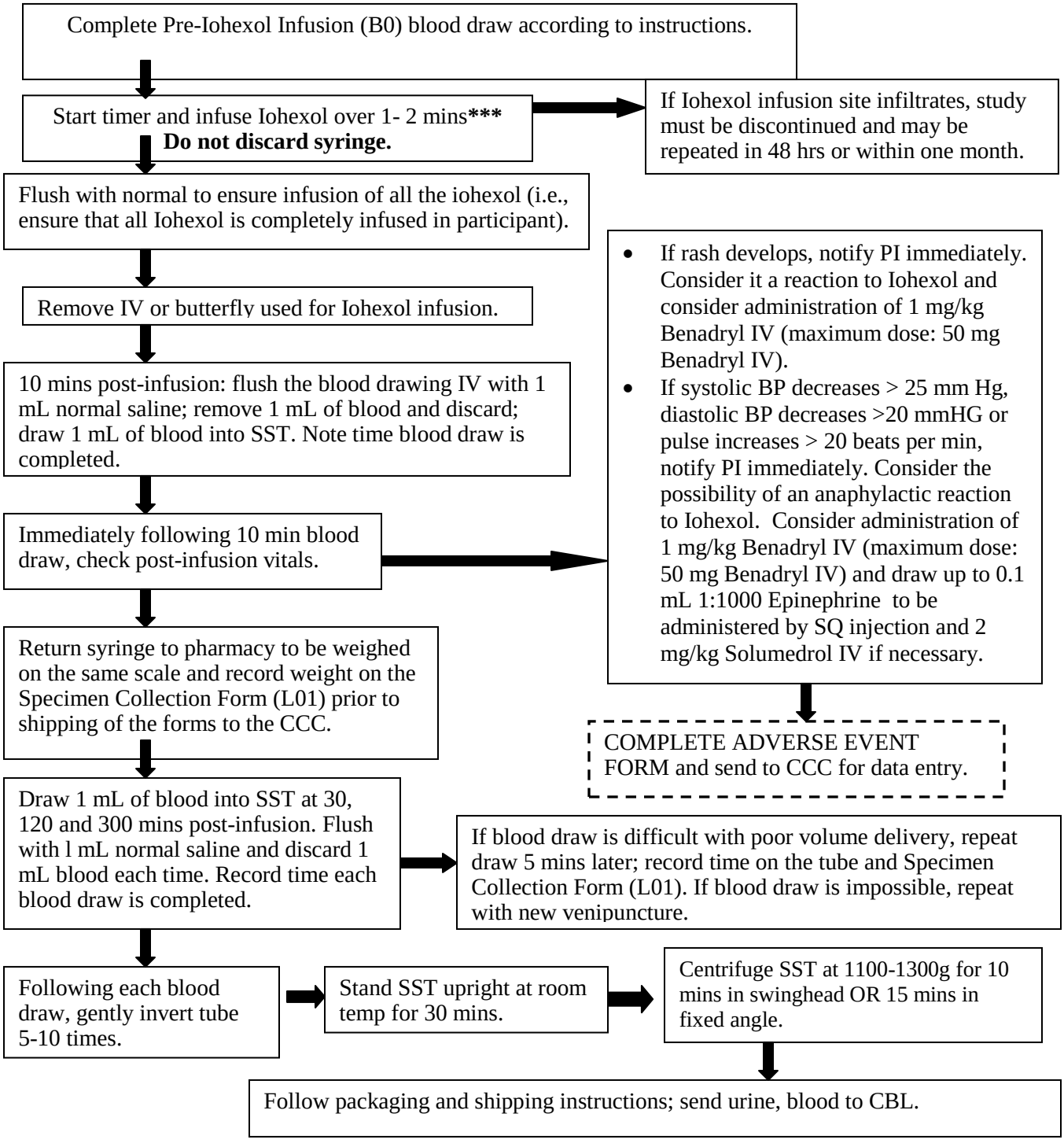
Instructions for Iohexol Infusion and GFR Blood Draws



*****Physician should be immediately available (in person or by phone) during Iohexol Infusion.**