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 6 / 0 1 / 0 8

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

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

The following samples should be collected.

Samples:	**Shipped to:**	**Shipped:**
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

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

Yes..... 1

No..... 2 **(Skip to B5)**

B3a. Make-up GFR date:

___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

***MAKE-UP GFR VISIT* PROMPT: COLLECT 1.0 mL OF BLOOD IN THE PROVIDED SST LABELED B0 BEFORE THE IOHEXOL INFUSION.**

(Remember to waste 1cc if the blood was not collected from a butterfly.)

B4. Indicate reason(s) for a Make-Up GFR visit: **(Circle "Yes" or "No" for each):**

	Yes	No
IV infiltration.....	1	2
Inability to successfully draw 4 blood samples for iohexol.....	1	2
Other reason.....	1	2 **(Skip to E1)**

Specify:_____ **(Skip to E1)**

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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 the central biochemistry laboratory.

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Pour 10 to 14.5 mL of urine into dark blue top urine collection tube (provided by CBL).

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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:**
B5. Urine Creatinine, Urine Protein, Urine Albumin (10.0 mL–14.5 mL in Dark Blue Top tube)	1 / 2 **(skip to c→)**	___ ___ **(skip to C1)**	i. Is this a first morning urine sample? 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 (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

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Complete Time=0 (Pre-Iohexol Infusion) blood draw according to MOP instructions/flowchart on page 4.
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**: 12 mL

Immediately transfer 1 mL of whole blood into lavender-top tube for local CBC and 3 mL for local renal panel. Process and send to local lab for analysis and complete CBC and Local Renal Panel results forms (L04 & L03).

Using 18-22 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 renal panel; draw 8 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 renal panel; draw 8 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 and not more than 1 hour (60 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.

You must send hemolyzed sample to CBL for Pre-Iohexol level. Also, if the sample is **GROSSLY HEMOLYZED (Dark Red),** collect 2.5 mL of additional blood at **B1**, **B2**, **B3** or **B4**. Centrifuge and then transfer serum into the extra Clear-Top with Red Ring Tube provided.

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

B0
Using the disposable pipette, pipette 0.5 mL of serum into Clear-Top with Red Ring Transport Tube labeled "B0" for B0 sample.

CBL Chemistries
Using the disposable pipette, pipette 3.0 mL of serum into Clear-Top with Red Ring Transport Tube labeled "Serum CBL" for CBL chemistries, Serum Creatinine, iron sample.

Cystanin C
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 to CBL every four months. 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 and ship to CBL with accompanying forms. No FRIDAY shipments. Ship on next business day

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.

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

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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/Iron 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).....1 Moderately (Red/Light Red).....2 Slightly (Pink)..... .....3 Not Hemolyzed (Yellow).....4
C3. Cystatin C (1.0 mL in Tiger Top SST)	1 **(skip to c→)** 2	___ ___ **(skip to C4)**	Date Frozen: ___ ___ /___ ___ /___ ___ ___ ___ 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. Local Renal Panel (3.0 mL in Local SST)	1 **(skip to D2)** 2	___ ___ **(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.**
- **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).**

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 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 AT 1100-1300 g (3000 rpm with 10 cm radius) FOR AT LEAST 10 MINS IN SWINGHEAD OR 15 MINS 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 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.**

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(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:	___ ___

	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:** **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 2 hrs** (120 min):	___ **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 5 hrs** (300 min):	___ **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

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

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Complete pre-iohexol infusion (B0) blood draw according to instructions

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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 must occur within 3 months of initial visit

→ 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.

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COMPLETE ADVERSE EVENT FORM and send to CCC for data entry

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

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10 minutes post-infusion
V1A: 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**

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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

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V1A/V2: 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

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

→ 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.

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Following each blood draw: gently invert tube 5-10 times → Stand SST upright at room temp for 20-30 minutes, but no longer than 1 hour → Centrifuge at 1100-1300 g for 10 minutes in swinghead or 15 minutes in fixed angle*

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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