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 3 / 0 1 / 1 8a

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)**
Urine	**CBL**	**IMMEDIATELY**
Iohexol Blood*	**CBL**	**IMMEDIATELY**

*** COLLECT IOHEXOL BLOOD DRAW: Only if Cohort 3 participants who consent to iohexol protocol or Cohorts 1 & 2 participants had previous iGFR>90**

BATCHED SAMPLES SHOULD BE SHIPPED QUARTERLY (Jan, Apr, July or Oct) OR MORE OFTEN IF DESIRED BY THE SITE COORDINATOR!

Samples should NOT be stored for more than six (6) months. For specific questions, contact your CCC prior to shipment.

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 STUDY VISIT DATE.

If performing iohexol protocol, B2 MUST BE COMPLETED BEFORE IOHEXOL TESTING IS INITIATED.

B2. a. Urine pregnancy test date: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

b. Urine pregnancy results:

Positive..... 1 **(END; COMPLETE TRANSITIONAL (TRS03) FORM)**

Negative..... 2

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.

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

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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; 2 = Difficult Urine Collection; 3 = Participant Refused; 4 = Collection Contamination; 5 = Inadvertently Destroyed; 6 = Oversight; 7=Insufficient Volume

Sample Type (Required Volume):	(a) Sample Obtained: Yes	(a) Sample Obtained: No	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
B3. Urine Creatinine, Urine Protein, Urine Albumin (1 mL–10 mL)	1 **(skip to c→)**	2	___ ___ **(skip to C1)**	i. Is this a first morning urine sample? Yes.....1 No.....2 ii. Time of Collection: __ __ : __ __ 1 = am, 2 = pm

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

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

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)***

2 **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.**

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SECTION C: Visit 1a BLOOD DRAW PROCESSING

Initial blood draw with **Syringe(s)**

Immediately transfer 1 mL of whole blood into lavender-top tube for local CBC and 1.5 mL for local renal panel. Process and send to local lab for analysis and complete CBC and Local Renal Panel results forms (L04 & L03).

OR

Initial blood draw with **Vacutainer Method**: draw 1 mL directly into lavender-top tube for local CBC; draw 1.5 mL directly for local renal panel; draw 2 mL (3 mL if performing the iohexol protocol) directly into tiger-top SST

OR

Initial blood draw with **Butterfly**: draw 1 mL directly into lavender-top tube for local CBC; draw 1.5 mL directly for local renal panel; draw 2 mL (3 mL if performing iohexol protocol) directly into tiger-top SST

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

Invert the 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).

Centrifuge SST at MAX SPEED between 1100-1300 g (3000rpm with 10cm radius rotor) 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. Also, if the sample is **GROSSLY HEMOLYZED (Dark Red),** collect 1 mL of additional blood in a SST. Centrifuge and then transfer serum into the extra Orange Top Transport Tube provided.

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

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

For IOHEXOL STUDY VISITS ONLY:
B0 sample

Using the disposable pipette, pipette 0.5 mL of serum into Round-bottom Orange Top Transport Tube labeled "B0" for Iohexol Blank (B0) sample. 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.

CBL Studies

Using the disposable pipette, pipette 0.5 mL of serum into Orange Top Transport Tube labeled "Serum CBL" for CBL renal/uric acid. 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.

Cystatin 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 every four months to the CBL. When shipper is needed, complete "CBL Dry Ice Shipper Request Form" on the CKiD website: https://statepi.jhsph.edu/ckid/coordinator-resources/
Then, follow packaging instructions and ship to CBL with accompanying forms. **No FRIDAY shipments.** Ship

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

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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	4 = Red Blood Cell Contamination	7 = Exceeds maximum allowable volume
	2 = Difficult Blood Draw	5 = Inadvertently Destroyed	
	3 = Participant Refused	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/ 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 **(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 (1.5 mL in Local SST)	1 **(skip to D2)** 2	___ ___ **(skip to D2)**	**N/A**

Sites can obtain results for lab values that have been identified as “KEY VARIABLES”. To obtain results, go the CKiD Nephron Website: **https://statepiaps8.jhsph.edu/nephron/groups/aspproc/**, click on “Report Menu” and choose the appropriate lab report (i.e., Selected Renal Panel Lab Variables Report.)

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 → **Complete Local Urine Assay Results Form L06 ONLY if local labs are CLINICALLY INDICATED**

No..... 2

IOHEXOL PROTOCOL

D3. Is the participant completing iohexol study visit? Yes, consent obtained..... 1

No..... 2 → **(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 Iohexol "B0" Blank sample) should be collected for Iohexol-Based GFR.

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 PARTICIPANT'S GFR.

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

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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
--OR---
Use butterfly for pre-iohexol and individual blood draw sticks; use tape to stabilize butterfly for Iohexol infusion

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Complete pre-iohexol infusion 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 should occur within 3 months of initial.

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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
CHECK POST-INFUSION VITALS
DO NOT DRAW BLOOD AT 10 MINUTES

→ If rash develops, consider it a reaction to iohexol and **notify PI immediately**. Consider administering 1mg/kg Benadryl IV (maximum dose 50mg) or follow your local institution guidelines.

→ 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 or follow your local institution guidelines.

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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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Draw 1 ml of blood into SST at 120 mins (B1), and 300 mins (B2).

*For IV ONLY: Discard initial 1 mL blood waste at each blood draw (or per device guidelines)

*For IV ONLY: Flush after each blood draw with at least 3 mL normal saline

*Record the time each blood draw is completed

→ 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.

→ COMPLETE ADVERSE EVENT FORM and send to CCC for data entry

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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*

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Transfer serum into the cryovial labeled "Iohexol Serum."

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Following packaging and shipping instructions; send urine, blood and copies of completed shipping form(s) & 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

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 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) 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 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, or follow your local institution guidelines.**

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

SPECIMEN COLLECTION FORM for Visit 1a (L01)

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 Draw:** **Yes** **No**	**(iv) Blood Drawn via Venipuncture** **Yes** **No**	**(v) Blood Volume Collected (1 mL):**	**(vi) Centrifuged at Clinical Site:** **Yes** **No**
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** 2nd 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** 2nd attempt:	___ **hr** ___ ___ mins	__ __ : __ __ 1 = AM 2 = PM	1 2	1 2	___ . ___ mL	1 2