SPECIMEN COLLECTION FORM for ODD Follow-up Visits (3, 5, 7…) (L31)

CKiD Chronic Kidney Disease in Children Cohort Study
SECTION A: GENERAL INFORMATION

A1. PARTICIPANT ID: AFFIX ID LABEL OR ENTER NUMBER IF ID LABEL IS NOT AVAILABLE

|__| - |__|__| - |__|__|__|

A2. CKiD VISIT #: 0 3

A3. FORM VERSION: 1 0 / 0 1 / 1 2

A4. SPECIMEN COLLECTION DATE: ___ ___/ ___ ___/ ___ ___ ___ ___
M M D D Y Y Y Y

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

The following sample should be collected.

Samples:	Shipped to:	Shipped:
Serum	**CBL**	**IMMEDIATELY**
Serum	**CBL**	**BATCHED (Ship in Jan, Apr, Jul or Oct)**
Plasma	**CBL**	**BATCHED (Ship in Jan, Apr, Jul or Oct)**
Urine	**CBL**	**IMMEDIATELY**
***Iohexol Blood**	**CBL**	**IMMEDIATELY**

***ONLY COLLECT IOHEXOL BLOOD IF THIS IS AN ACCELERATED STUDY VISIT.**

Please refer to questions 22 on the Eligibility Form to determine if biological consent was obtained.

Depending on the type of consent, the following samples may or may not be collected:

Samples:	Shipped to:	Shipped:
Serum (Biological)	***NIDDK Biosample Repository***	**BATCHED (Ship in Jan, Apr, Jul or Oct)**
Plasma (Biological)	***NIDDK Biosample Repository***	**BATCHED (Ship in Jan, Apr, Jul or Oct)**
Urine (Biological)	***NIDDK Biosample Repository***	**BATCHED (Ship in Jan, Apr, Jul or Oct)**
****Whole Blood (Genetic)***	***Rutgers Repository***	***IMMEDIATELY***

***ONLY collect whole blood for Genetic Repository, if sample was not collected at V1b OR if sample collected at V1b was inadequate.**

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 one year.
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.

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

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 central biochemistry laboratory (containers were shipped in batches to each site).

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
	2 = Difficult Urine Collection	4 = Collection Contamination	6 = Oversight

	Sample Type (Required Volume):	**(a) Sample Obtained:** Yes	No	**(b) If No, specify reason** ***SEE CODE LIST ABOVE**	**(c) Additional Requirements:**
B3.	Urine Creatinine, Urine Protein, Urine Albumin (CBL) (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

SPECIMEN COLLECTION FORM for ODD Follow-up Visits (3, 5, 7…) (L31)

SECTION C: Visit 3 BLOOD DRAW

For Initial Blood Draw with Syringe, Vacutainer OR Butterfly Method: Select the Type of Consent Obtained (options 1 through 4):

ONLY collect whole blood for Genetic Repository, if sample was not collected at V1b or sample collected at V1b was inadequate.

For irregular visits, an additional 1.0mL of blood should be collected in the Tiger Top SST for Iohexol Blank (B0) blood sample.

1 **If participant consented to both BIOLOGICAL AND GENETIC samples:**

Collect **24.3-25.3** mL if participant is **< 30 kg** **OR** **30.3-31.3** mL if participant is **≥ 30 kg**.

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

- If not collected at V1b - 7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository
  (**ACD Tubes must be COMPLETELY FILLED**)
- 10 mL into (2) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 4 mL into two (2) PSTs for CBL and NIDDK Biosample Repository
- 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)***

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

- If not collected at V1b - 7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository
  (ACD Tubes must be COMPLETELY FILLED)
- 14 mL into (2) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 6 mL into two (2) PSTs for NIDDK Biosample Repository
- 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 **If participant consented to BIOLOGICAL samples ONLY:**

Collect **16.5-17.5** mL if participant is **< 30 kg** **OR** **22.5-23.5** mL if participant is **≥ 30 kg**.

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

- 10 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR
- 4 mL into two (2) PSTs for CBL and NIDDK Biosample Repository
- 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)***

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

- 14 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR
- 6 mL into (2) PST for NIDDK Biosample Repository
- 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)***

3 **If participant consented to GENETIC samples ONLY, collect 15.3-16.3 mL from all participants** (regardless of weight)**:**

Immediately transfer or draw:

- If not collected at V1b - 7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository (ACD Tubes must be COMPLETELY FILLED)
- 4mL into (2) Tiger-Top SST for CBL
- 1 mL into PST 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)***

4 **If participant did NOT consent to BIOLOGICAL samples and Genetic samples:**

Collect **7.5-8.5** mL from all participants (regardless of weight) as specified below.

Immediately transfer (using 18 gauge needle) or draw:

- 4 mL into (2) Tiger-Top SSTs for CBL
- 1 mL into PST 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)***

SECTION C: Visit 3 BLOOD DRAW PROCESSING

CBL & NIDDK BR (Serum)

Invert the Tiger Top 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 1100-1300g (3000rpm with 10cm radius rotor) for 10 mins in swinghead OR 15 mins in fixed angle. *If incomplete separation, centrifuge again 10-15 mins.

You must send hemolyzed sample to CBL for. Also if the sample is **GROSSLY HEMOLYZED (Dark Red),** then collect 1 mL of additional blood in a SST. Centrifuge and then transfer serum into the extra Orange Top Transport Tube provided.

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

CBL Studies
Using the disposable pipette, pipette 0.5 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 and urine. **No FRIDAY shipments.** Refrigerate specimen and ship on next business day.

NIDDK (Serum)
Pipette 3mL (<30kg) or 5mL (≥30kg) serum into clear top cryovial for NIDDK BR (use different pipettes for serum and plasma).
**If there is any extra serum, then pipette the extra serum into the clear top cryovial marked "SERUM (Extra).*

Store sample in freezer at -70ºC or lower, batch up to 40 samples and ship during **Jan, Apr, Jul and Oct**. When shipper is needed, complete "NIDDK BR Shipper Request Form" on 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 to notify Heather Higgins, Sandra Ke and KIDMAC that sample(s) have been shipped to NIDDK BR.

iPTH/hsCRP
Pipette 0.5 mL of serum into a red top cryovial tube for CBL iPTH &, hsCRP

Vitamin D
Pipette 0.5 mL of serum into a red top cryovial for CBL Vitamin D

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 -70ºC or lower and batch up to 20 samples and ship quarterly during the months of **January, April, July and October**. When shipper is needed, complete "CBL Dry Ice 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.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website to notify CBL and KIDMAC that sample(s) have been shipped to CBL.

CBL & NIDDK BR (Plasma)

Invert each PST 8-10 times gently to mix.

Centrifuge each PST at 1100-1300g for 10 mins (swinghead) **OR** 15 mins (fixed angle).

FGF-23
Pipette 0.5 mL of plasma into a cryovial with green cap insert for CBL FGF-23

Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) plasma into cryovial with green cap insert (use different pipettes for serum and plasma).
**If there is any extra plasma, then pipette the extra plasma into the green cap insert cryovial marked "PLASMA (Extra)".*

Store sample in freezer at -70ºC or lower, batch up to 40 samples and ship during the months of **Jan, April, July and Oct**. When shipper is needed, complete "NIDDK BR 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 to notify Heather Higgins, Sandra Ke and KIDMAC that sample(s) have been shipped to NIDDK BR.

RUTGERS

Invert each of the 3 pediatric yellow-top ACD Tubes 6 times gently to mix blood with additives.

Keep tubes at room temperature. **DO NOT FREEZE.**

Follow packaging instructions, complete RUCDR Collection Form and ship immediately to Rutgers Repository with accompanying forms. **Specimen can be shipped on Friday.**

Complete "On-line Shipping Form" on CKiD website to notify KIDMAC that sample(s) have been shipped to Rutgers.

SECTION C: Visit 3 BLOOD DRAW AND PROCESSING

C1. ACTUAL TIME OF BLOOD DRAW ____ ____ : ____ ____ 1 = AM 2 = PM

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:**
C2a. Renal/Uric Acid Chemistries (1.0* mL in Tiger Top SST)	1 **(skip to c→)**	2	__ __ **(skip to C2b)**	i. Indicate the appearance of the serum after centrifuging. Grossly (Dark Red).....1 Moderately (Red/Light Red).....2 Slightly (Pink)..... .....3 Not Hemolyzed (Yellow).....4
C2b. Cystatin C (1.0 mL in Tiger Top SST)	1 **(skip to c→)**	2	__ __ **(skip to C3)**	Date Frozen: __ __ / __ __ / __ __ __ __ M M D D Y Y Y Y
C3a. Serum for iPTH, hsCRP & Vitamin D (2.0 mL of blood in Tiger Top SST)	1 **(skip to c→)**	2	__ __ **(skip to C3b)**	Date Frozen: __ __ / __ __ / __ __ __ __ M M D D Y Y Y Y
C3b. Plasma for FGF-23 (1.0 mL of blood in PST)	1 **(skip to c→)**	2	__ __ **(skip to C4a)**	Date Frozen: __ __ / __ __ / __ __ __ __ M M D D Y Y Y Y
C4a. Local CBC (1.0 mL in Lavender Top tube)	1 **(skip to C4b)**	2	__ __ **(skip to C4b)**	**N/A**
C4b. Local Renal Panel (1.5 mL in Local SST)	1 **(skip to C5)**	2	__ __ **(skip to C5)**	**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://statepiaps.jhsph.edu/nephron/groups/aspproc/**, click on “Report Menu” and choose the appropriate lab report (i.e., Selected Renal Panel Lab Variables Report.)

* For irregular visits, an additional 1.0mL should be collected in the Tiger Top SST for Iohexol Blank (B0) blood sample.

C5. Did the participant consent to have biological samples (i.e., serum, plasma and urine) stored at NIDDK Biosample Repository?

Yes..... 1

No..... 2 **(Skip to E1)**

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:**
C6. Serum for NIDDK Biosample Repository (**6.0 mL or **10.0 mL of blood in Tiger Top SST)	1 **(skip to c→)**	2	___ ___ **(skip to C7)**	Date Frozen: ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y
C7. Plasma for NIDDK Biosample Repository (***3.0 mL of blood (1) Green Top or ***5.0 mL (2) Green Top PSTs)	1 **(skip to c→)**	2	___ ___ **(skip to D1)**	Date Frozen: ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y

** Collect 6.0 mL of whole blood for children < 30 kg and 10.0 mL for children ≥ 30 kg

*** Collect 3.0 mL of whole blood for children < 30 kg and 5.0 mL for children ≥ 30 kg

SECTION D: Visit 3 URINE COLLECTION AND PROCESSING FOR REPOSITORY

Collect FRESH urine into an initial urine collection cup or hat (provided by the site).

Pour 15-60 mL (preferably 60 mL) of FRESH urine into 90 mL urine collection cup with 4 protease inhibitor tablets. Do not fill the urine past the 60 mL mark on the collection cup. One protease inhibitor tablet should be used for 10-15 mL of urine **(see Table A)**. For example if 30 mL of urine is collected, ONLY 2 PI tablets are needed. (Like all unused supplies, **unused protease inhibitor tablets should be returned to the CBL**.)

TABLE A:

Urine Volume	# of Protease Inhibitor Tablets
10 – 15 mL	**1**
16 – 30 mL	**2**
31 – 45 mL	**3**
46 – 60 mL	**4**

Invert the urine cup gently 5 – 10 times.

The PROTEASE INHIBITOR TABLET(s) MUST BE **COMPLETELY** DISSOLVED in the urine.

Once the protease inhibitor tablets are completely dissolved, pour urine into up to six (6) 10 mL urine centrifuge tubes. (**For each tube:** remove yellow top cap, pour urine into tube and SCREW cap back onto tube.) Place no more than 10 mL in each tube.

– OR –

Sites may also substitute with tubes normally used to centrifuge urine at site.

Centrifuge urine tube(s) at MAX SPEED between 1100-1300g (3000rpm with 10cm radius rotor) for 10 mins (swinghead units) **– OR –** 15 mins (fixed angle units).

Decant (pour off) the supernates (liquid reaction) into up to seven (7) 10 mL urine cryovials. Pour no more than 9 mL of urine into each 10 mL cryovial to allow for expansion.

Check that all information is correct on the urine cryovials, promptly freeze and store sample(s) at -70ºC or lower. Batch samples and ship at least quarterly (include maximum of 36 cryovial shipper. When shipper(s) is needed, complete *"NIDDK Shipper Request Form"* on CKiD website: http://www.statepi.jhsph.edu/ckid/admin/. Then, follow packaging instructions.

When pickup has been scheduled, complete *"Online Shipping Form"* on CKiD website to notify Heather Higgins and KIDMAC that sample(s) have been shipped to NIDDK BR.

Reasons Code List*:	1= Not required	2 = Difficult Urine Collection	3 = Participant Refused	4 = Collection Contamination	5 = Inadvertently Destroyed	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:**
D1. Urine for NIDDK Biosample Repository (15.0 - 60.0 mL of urine in specimen container and transferred into collection cup with protease inhibitors)	1 **(skip to c→)**	2	___ ___ **(skip to D2→)**	i. Was supernate decanted into urine transport cryovials? Yes.....1 No.....2 ii. Date Frozen: ___ ___ /___ ___ /___ ___ ___ ___ M M D D Y Y Y Y

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 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: WHOLE BLOOD FOR GENETIC REPOSITORY

BLOOD FOR THE GENETIC REPOSITORY SHOULD BE SHIPPED ONLY IF THE SAMPLE WAS NOT COLLECTED AT V1B OR IF THE SAMPLE OBTAINED AT V1B WAS INADEQUATE (i.e, cell lines were not immortalized).
If participant has consented to have blood stored at Rutgers but it is not necessary to collect the blood for the Genetic Repository, Code question E2b as "01."

E1. Did the participant consent to have whole blood stored at Rutgers, the Genetic Repository?
Yes..... 1
No..... 2 **(Skip to E3)**

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:**
E2. Whole Blood for Rutgers Cell & DNA Repository (7.8 mL of blood in 3 pediatric (2.6 mL) Yellow Top ACD tubes)	1 **(skip to c→)**	2	___ ___ **(skip to E3)**	i. Date of Blood Draw: ___ ___ /___ ___ /___ ___ ___ ___ M M D D Y Y Y Y ii. Blood Drawn By : ____ ____ (initials) iii. Gender of participant : Male.....1 Female.....2 iv. Age of participant : ____ ____ years

VISIT TYPE

E3. Is this an irregular (accelerated) study visit?
Yes..... 1
No..... 2 → **(END Form)**

PREGNANCY TEST AND FIRST MORNING URINE COLLECTION

E4. Is participant a female of child-bearing potential?
Yes..... 1 **(See PROMPT Below)**
No..... 2 **(Skip to F1)**

PROMPT: QUESTION E5 IS FOR FEMALE PARTICIPANTS OF CHILD-BEARING POTENTIAL ONLY. URINE PREGNANCY TEST DATE MUST FALL WITHIN 72 HOURS BEFORE GFR TESTING DATE.

E5. 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

ONLY COMPLETE SECTIONS F & G IF THIS IS AN IRREGULAR STUDY VISIT.

For an irregular study visit, additional blood (including blood for the Iohexol "B0" Blank sample)should be collected for Iohexol-Based GFR.

SECTION F: IRREGULAR VISIT INFUSION SYRINGE WEIGHT

F1. **SCALE MUST FIRST BE ZEROED BEFORE WEIGHING. REMOVE ALUMINUM FOIL PRIOR TO WEIGHING THE SYRINGE. THE SAME SCALE MUST BE USED TO WEIGH THE SYRINGE PRE AND POST IOHEXOL 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 G: IRREGULAR STUDY VISIT

IOHEXOL – Refer to Instructions for Iohexol Infusion and GFR Blood Draws Flow Chart on Page 12

- **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

G1. 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.**
- **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.**

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(i) Post Vitals:		
G2a.	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:	___ ___

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
G3a.	**B1 2 hrs** (120 min):	___ **hr** ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1 **(Skip to b)**	2			___ . ___ mL	1 **(Skip to G4a)**	2 **(Skip to G4a)**
b.	**B1** 2nd attempt:	___ **hr** ___ ___ mins	___ ___ : ___ ___ 1 = AM 2 = PM	1	2	1	2	___ . ___ mL	1	2
G4a.	**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	1	2	___ . ___ mL	1	2

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

↓

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).

→ 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

↓

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).

*For IV ONLY: Discard initial 1 mL blood waste at each blood draw

*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.

↓

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."

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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