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 #: | <u>0</u> <u>3</u> | | | |
| A3. | FORM VERSION: | <u>1</u> <u>1</u> / <u>0</u> <u>1</u> / <u>1</u> <u>0</u> | | | |
| A4. | SPECIMEN COLLECTION DATE: | $\frac{}{M} \frac{}{M} \frac{}{D} \frac{}{D} \frac{}{D} \frac{}{Y} \frac{}{Y} \frac{}{Y} \frac{}{Y} \frac{}{Y}$ | | | |
| A5. | FORM COMPLETED BY: (INITIALS) | | | | |
| A6. | Is this study visit an irregular (ac | celerated) visit? Yes | | | |
| The | o following sample should be co | allacted | | | |

i ne following sample snould be collected.

Samples: Shipped to: Shipped: **IMMEDIATELY** Serum CBL

CBL **BATCHED** (Ship in Jan, Apr, Jul or Oct) Serum Plasma CBL BATCHED (Ship in Jan, Apr, Jul or Oct)

Urine CBL IMMEDIATELY CBL **IMMEDIATELY** *lohexol Blood

*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.

SECTION B: PREGNANCY TEST AND FIRST MORNING URINE COLLECTION

| 1. | ls p | participant a female of child-bearing | potential? | | | |
|--------|-------|--|------------------------------|--|--|-----------------|
| | | S | | elow) | | |
| | | QUESTION B2 IS FOR FEMALE I REGNANCY TEST DATE MUST FA | | | OTENTIAL ONLY. | |
| 32. | a. | Urine pregnancy test date: | /// | <u> </u> | | |
| | b. | Urine pregnancy results: | | | | |
| | | Positive Negative | 1 (END; COMPLE) 2 | TE DISENROLLMENT | FORM) | |
| | | e collected at home in the specimen contain | ner that was shipped to | | sit. IF URINE WAS NOT | |
| collec | ct FF | RESH urine into a specimen container pro | vided by central bioch | emistry laboratory (contai | ners were shipped in batch | es to each site |
| | | Pour 10 to 1 | 4.5 mL of urine into | the CBL transport tul | be. | |
| C] | hecl | that all information is correct on th | e urine collection tu | be and follow packagi | ng instructions and ship | to CBL. |
| Reas | sons | Code List*: 1= Not required | 3 = Participant | Refused 5 | 5 = Inadvertently Destroye | ed |
| | | 2 = Difficult Urine Collect | ion 4 = Collection (| Contamination 6 | S = Oversight | |
| | | Sample Type (Required Volume): | (a) Sample Obtained: Yes No | (b) If No, specify reason *SEE CODE LIST ABOVE | (c) Additional Requiren | nents: |
| B3. | | 1 st Morning Urine (Urine Creatinine, Urine Protein, Urine Albumin) | 1 2 (skip to c→) | (skip to C1) | i. Is this a first morning urin Yes1 No2 | ne sample? |
| | | (10.0 mL-14.5 mL in Light Blue Top tube) | | | ii. Time of Collection: : 1 = am, 2 | = pm |

SECTION C: Visit 3 BLOOD DRAW

For Initial Blood Draw with <u>Syringe</u>, <u>Vacutainer</u> OR <u>Butterfly</u> Method: Select the Type of Consent Obtained (options 1 through 4): <u>ONLY collect whole blood for Genetic Repository</u>, if sample was not collected at V1b or sample collected at V1b was inadequate.

If participant consented to both BIOLOGICAL AND GENETIC samples:

Collect 28.3-30.8 mL if participant is < 30 kg OR 32.3-34.8 mL if participant is $\ge 30 \text{ kg}$.

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)

- 12.5 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)
- 3 mL in another tube (not provided) for local Renal Panel
- 2.5 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)

- 14.5 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)
- 3 mL in another tube (not provided) for local Renal Panel
- 2.5 mL of additional blood in SST for CBL (if initial sample is grossly hemolyzed)

2 If participant consented to BIOLOGICAL samples ONLY:

Collect 20.5-23.0 mL if participant is < 30 kg OR 24.5-27.0 mL if participant is $\ge 30 \text{ kg}$.

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

- 12.5 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)
- 3 mL in appropriate tube (not provided) for local Renal Panel
- 2.5 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:

- 14.5 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)
- 3 mL in appropriate tube (not provided) for local Renal Panel
- 2.5 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)

3 If participant consented to GENETIC samples ONLY, collect 22.3 – 24.8 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)
- 9.5 mL 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)
- 3 mL in another tube (not provided) for local Renal Panel
- 2.5 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 14.5-17.0 mL from all participants (regardless of weight) as specified below.

Immediately transfer (using 18 gauge needle) or draw:

- 9.5 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)
- 3 mL in another tube (not provided) for local Renal Panel
- 2.5 mL of additional blood in SST for CBL (if initial sample is GROSSLY HEMOLYZED)

SECTION C: Visit 3 BLOOD DRAW PROCESSING CBL & NIDDK BR (Plasma)

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 *If incomplete separation, centrifuge again 10-15 mins. swinghead OR 15 mins in fixed angle.

You must send hemolyzed sample to CBL for. Also if the sample is GROSSLY HEMOLYZED (Dark Red), then collect 2.5 mL of additional blood in a SST. Centrifuge and then transfer serum into the extra Clear-Top with Red Ring Tube provided.

CBL Studies

Using the disposable pipette, pipette 3.0 of serum into Clear-Top with red ring Transport Tube labeled "Serum CBL" for CBL renal/iron chemistries). Follow packaging instructions and ship to CBL with accompanying forms and urine. No FRIDAY shipments. Refrigerate specimen and ship on next business day.

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

NIDDK (Serum)

Pipette 1.5mL (<30kg) or 2.5mL (≥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 -70°C 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.

Pipette 0.75 mL of serum into a redcryovial tube for CBL iPTH &. hsCRP

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

Store sample in freezer at -70°C 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.

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

0.5 mL of

Pipette

plasma

into a

cryovial

for CBL

FGF-23

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

RUTGERS

Keep tubes at room temperature. DO NOT FREEZE.

Follow packaging instructions and ship Pipette 1.5mL (<30kg) or immediately to 2.5mL (≥30kg) plasma into Rutgers Repository cryovial with green cap insert with accompanying (use different pipettes for forms. **Specimen** can be shipped on *If there is any extra plasma, Friday. then pipette the extra plasma into

Store sample in freezer at -70°C 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:

serum and plasma).

the green cap insert cryovial

marked "PLASMA (Extra)".

http://www.statepi.jhsph.edu/ckid/admin/ Then, follow packaging instructions. Complete "On-line Shipping Form" on CKiD website to notify KIDMAC that sample(s) have been shipped to Rutgers. Also, notify Rutgers Repository by completing Shipping Blood log on Rutgers' website by clicking on the link: http://rucdr.rutgers.edu

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

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 Obtai <u>Yes</u> | ned: <u>No</u> | (b) If No, specify reason *SEE CODE LIST ABOVE | (c) Additional Requirements: | | |
|------|--|-----------------------------------|-------------------|--|---|--|--|
| C2a. | Renal/Iron Chemistries (6.0 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) | | |
| C2b. | Cystatin C (1.0 mL in Tiger Top SST) | 1 (skip to c→) | 2 | (skip to C3) | Date Frozen: / | | |
| C3a. | Serum for iPTH, hsCRP & Vitamin D (2.5 mL of blood in Tiger Top SST) | 1 (skip to c→) | 2 | (skip to C3b) | Date Frozen: / | | |
| C3b. | Plasma for FGF-23 (1.0 mL of blood in PST) | 1 (skip to c→) | 2 | (skip to C4a) | Date Frozen: / | | |
| C4a. | Local CBC (1.0 mL in Lavender Top tube) | 1 (skip to C4b) | 2 | (skip to C4b) | N/A | | |
| C4b. | Local Renal Panel (3.0 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.)

| C5. | Did the participant consent to have biological sam | ples (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 Obta | ined: | (b) If No, specify reason *SEE CODE LIST ABOVE | (c) Additional Requirements: | | |
|-----|--|--------------------|-----------|--|---------------------------------|--|--|
| | | <u>Yes</u> | <u>No</u> | | | | |
| C6. | Serum for NIDDK Biosample Repository (**3.0 mL or **5.0 mL of blood in Tiger Top SST) | 1 (skip to c→) | 2 | (skip to C7) | Date Frozen: / | | |
| 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 3.0 mL of whole blood for children < 30 kg and 5.0 mL for children \geq 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 blue top 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:

of Protease
Inhibitor Tablets

10 - 15 mL
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 -70°C 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 3 = Participant 4 = Collection 5 = Inadvertently 6 = Oversight

Collection Refused Contamination Destroyed

| Sample Type | | (a) | | (b) | (c) | | | |
|-------------|---|-------------------|-----------|-----------------------|--|--|--|--|
| | (Required Volume in Top Color Tube Type): | Sample Obtained: | | If No, specify reason | Additional Requirements: | | | |
| | (| <u>Yes</u> | <u>No</u> | *SEE CODE LIST ABOVE | | | | |
| | 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? Yes1 No2 ii. Date Frozen: / / | | | |

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).

| UZ. | was a 1 morning drine protein to creat | 11 111 10 | 5 rau | o assay performed at the climical site's local laboratory: |
|-----|--|-----------|---------------|--|
| | Yes No | 1 2 | \rightarrow | Complete Local Urine Assay Results Form L06, ONLY if local labs are CLINICALLY INDICATED |

Was a 1st morning uring protoin to creatining ratio assay performed at the clinical site's local laboratory?

SECTION E: WHOLE BLOOD FOR GENETIC REPOSITORY

BLOOD FOR THE GENETIC REPOSITORY SHOULD BE SHIPPED ONLY IF THE SAMPLE <u>WAS NOT</u> 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? Yes1 | | | | | | | | |
|-----|----|--|--------------------------|----------------------------------|-----------------------------|--|--|--|--|--|
| | No | | 2 (5 | Skip to E3) | | | | | | |
| | F | 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): | | ined: | (b) If No, specify reason | (c) Additional Requirements: | |
|-----|--|--------------|-----------|------------------------------|---------------------------------|--|
| | | <u>Yes</u> | <u>No</u> | *SEE CODE LIST ABOVE | | |
| E2. | Whole Blood for Rutgers Cell & DNA Repository | 1 | 2 | | i. Date of Blood Draw: | |
| | (7.8 mL of blood in 3 pediatric (2.6 mL) Yellow Top | (skip to c→) | | | | |
| | ACD tubes) | | | (skip to E3) | / | |
| | | | | | M M D D Y Y Y Y | |
| | | | | | ii. Blood Drawn By : (initials) | |
| | | | | | iii. Gender of participant : | |
| | | | | | Male1 | |
| | | | | | Female2 | |
| | | | | | | |
| | | | | | iv. Age of participant : years | |

COPY THIS PAGE AND SHIPMENT TRACKING FORM (ST04) AND SEND TO RUTGERS WITH RUTGERS SPECIMEN.

| | s this an irregular (accelerated) study visit? Yes | 1 2 (END) | | | | | |
|-----|---|---------------------|--------|---|--|--|--|
| | | | | S AN IRREGULAR STUDY VISIT. I be collected for lohexol-Based GFR. | | | |
| | | | | JSION SYRINGE WEIGHT | | | |
| F1. | SCALE MUST FIRST BE ZEROED BEFORE WITHE SAME SCALE MUST BE USED TO WEIGH | | | LUMINUM FOIL PRIOR TO WEIGHING THE SYRINGE. 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 | Γ BE OBTAII | NED | N 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 | | | | | | |
| > C | EFORE INFUSING 5 mL OF IOHEXOL, SET TING OMPLETE INFUSION BETWEEN 1 TO 2 MINS EAVE TIMER RUNNING THROUGHOUT IOHEX | | | BSEQUENT BLOOD DRAWS | | | |
| G1. | IOHEXOL INFUSION a. INFUSION START TIME: | _: | 1 = AM | 1 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 <u>AFTER</u> EACH BLOOD SAMPLE IS OBTAINED (i.e., B1, B2).

POST VITALS SHOULD BE TAKEN IMMEDIATELY AFTER THE 10 MINUTE BLOOD DRAW USING LOCAL BLOOD PRESSURE MEASUREMENT (i.e. DINAMAP)

- If rash develops after lohexol Infusion, consider it a reaction to lohexol 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 lohexol. 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: | | | | | | | | |
|------|---|--------|--|--|--|--|--|--|--|
| G2a. | Post- infusion blood pressure: | / | | | | | | | |
| b. | Post-infusion temperature: | 1 = °C | | | | | | | |
| 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 Bl Draw: Yes | | (iv) Blood Volume Collected (1 mL): | Centrifuged at | v) Clinical Site: 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 2 nd attempt: | hr | mins | : 1 = AM 2 = PM | 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) | 2 (END) |
| b. | B2 2 nd attempt: | hr | mins | : 1 = AM 2 = PM | 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 Complete pre-iohexol infusion blood draw according to instructions Start timer and infuse johexol 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 If rash develops, consider it a reaction to iohexol and REMOVED notify PI immediately. Consider administering 1mg/kg Benadryl IV (maximum dose 50mg). 10 minutes post-infusion If systolic BP decreases > 25 mm Hg, diastolic BP CHECK POST-INFUSION VITALS decreases > 20 mm Hg or pulse increases > 20 beats per DO NOT COLLECT BLOOD SAMPLE AT 10 MINUTES 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. 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 COMPLETE ADVERSE EVENT FORM and send to CCC for data entry Draw 1 mL of blood into SST at 120 mins (B1) and 300 mins (B2) post-infusion. If blood draw is difficult with poor volume *Discard initial 1 mL blood waste at each blood draw delivery, repeat draw 5 minutes later; *Record the time each blood draw is completed record time on Specimen Collection Form and tube. If blood draw is impossible, *Flush after each blood draw with at least 3 mL normal saline repeat with new venipuncture. Stand SST upright at room Centrifuge at MAX SPEED between 1100-Following each blood draw: temp for 30 minutes, but 1300 g for 10 minutes in swinghead or 15 gently invert tube 5-10 times no longer than 1 hour 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

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