

SPECIMEN COLLECTION FORM for EVEN Follow-up Post-Transplant Visit (TL21)

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 Post KRT VISIT #: _____

A3. FORM VERSION: 0 7 / 0 1 / 1 9a

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

A5. FORM COMPLETED BY (INITIALS): _____

At the Post-Transplant Visit, collect the following:

<u>Samples:</u>	<u>Shipped to:</u>	<u>Shipped:</u>
Serum	CBL	IMMEDIATELY
Serum	CBL	Batched (Ship in Jan, Apr, Jul or Oct)
Urine	CBL	IMMEDIATELY
Iohexol Blood	CBL	IMMEDIATELY

If consent is obtained for biological samples, collect the following:

<u>Samples:</u>	<u>Shipped to:</u>	<u>Shipped:</u>
Serum (Biological)	NIDDK Biorepository	Batched (Ship in Jan, Apr, Jul or Oct)
Plasma (Biological)	NIDDK Biorepository	Batched (Ship in Jan, Apr, Jul or Oct)
Urine (Biological)	NIDDK Biorepository	Batched (Ship in Jan, Apr, Jul or Oct)

**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.**

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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

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**Post-Transplant Visit
FIRST MORNING URINE COLLECTION for CBL**

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.

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	7 = Insufficient Volume
	2 = Difficult Urine Collection	4 = Collection Contamination	6 = Oversight	

Sample Type (Required Volume):	(a) Sample Obtained:		(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
	Yes	No		
B3. Urine Creatinine, Urine Protein (1 mL–10 mL)	1 (skip to c→)	2	_____ (skip to B4)	i. Is this a first morning urine sample? Yes.....1 No.....2 ii. Time of Collection: ____ : ____ 1 = am, 2 = pm

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).

B4. Was a urine protein to creatinine ratio assay performed at the clinical site's local laboratory?
 Yes..... 1 → **Complete Local Urine Assay Results Form**
 No..... 2 **L06 ONLY if local labs are CLINICALLY INDICATED**

SECTION C: POST-TRANSPLANT VISIT BLOOD DRAW

For Initial Blood Draw with Syringe, Vacutainer OR Butterfly Method: Select the type of consent obtained (options 1 through 2):

1 If participant consented to BIOLOGICAL samples:

Collect **16-17 mL** if participant is **< 30 kg** OR **22-23 mL** if participant is **≥ 30 kg**.

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

- 10.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK Biorepository
- 3 mL into (1) PST for NIDDK Biorepository
- 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:

- 14.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK Biorepository
- 5 mL into (2) PST for NIDDK Biorepository
- 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 did NOT consent to BIOLOGICAL samples:

Collect **7-8 mL** from all participants (regardless of weight) as specified below.

Immediately transfer (using 18 gauge needle) or draw:

- 4.5 mL into (1) Tiger-Top SSTs for CBL (renal panel, uric acid, cystatin C & lipid panel)
- 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: POST-TRANSPLANT VISIT BLOOD DRAW PROCESSING

Invert the SST 5 times & PST 8-10 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 & PST at MAX SPEED between 1100-1300g (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. If participant has eaten, aliquot hemolyzed sample for fasting lipid profile and send 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.

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

For IOHEXOL STUDY 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 0.75 mL of serum into Orange Top Transport Tube labeled "Serum CBL" for CBL renal/uric acid and lipids. 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.

iPTH/hsCRP

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

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 "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 on next business day.

Cystatin C

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

NIDDK BR (Serum & Plasma)

Pipette 3 mL (<30kg) or 5 mL (≥ 30kg) of serum into clear top cryovial & 1.5 mL (<30kg) or 2.5 mL (≥ 30kg) of plasma into cryovial into green cap insert (use different pipettes for serum and plasma). *If there is any extra serum and/or plasma, then pipette the extra serum into the clear top cryovial marked "NIDDK BR SERUM" and the extra plasma in green cap insert cryovial marked "PLASMA (Extra)." Complete the SM01 form, store sample in freezer at -70°C or lower, batch up to 40 samples and ship on dry ice quarterly (**Jan, April, July and Oct**) to the NIDDK BR. **No Thursday/Friday shipments.** When shipper is needed, complete "NIDDK BR Dry Ice Shipper Request Form" on CKiD website: <https://statepi.jhsph.edu/ckid/coordinator-resources/>. Then, follow packaging instructions.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: <https://statepi.jhsph.edu/ckid/coordinator-resources/> to notify the appropriate personnel from the CBL and the NIDDK BR.

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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 = Exceed 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:	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
	Yes No		
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 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
C5. Serum for Fasting Lipid Panel (0.5 mL in Tiger Top SST)	1 (skip to c→) 2	_____ (skip to C6)	Did the participant fast after midnight? Yes.....1 No.....2*
C6. Serum for ipth & hsCRP (1.0 mL in Tiger Top SST)	1 (skip to c→) 2	_____ (skip to D1)	Date Frozen: ____/____/____ M M D D Y Y Y Y

*If the participant did not fast, the Nephron Lipid Report will indicate that the participant did not fast.

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: NIDDK BIOREPOSITORY

D1. Did the participant consent to have biological samples (i.e., serum, plasma and urine samples) stored at the NIDDK Biorepository?

Yes..... 1

No..... 2 (Skip to E2)

Reasons Code List* :	1= Not required 2 = Difficult Blood Draw 3 = Participant Refused	4 = Red Blood Cell Contamination 5 = Inadvertently Destroyed 6 = Oversight	7 = Exceed maximum allowable volume
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Sample Type (Required Volume in Top Color Tube Type):	(a) Sample Obtained:		(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
	Yes	No		
D2. Serum for NIDDK Biorepository (**6.0 mL or **10.0 mL of blood in Tiger Top SST)	1 (skip to c→)	2	_____ (skip to D3)	Date Frozen: ____/____/_____ M M D D Y Y Y Y
D3. Plasma for NIDDK Biorepository (***3.0 mL of blood in one Green Top or ***5.0 mL in two Green Top PSTs)	1 (skip to c→)	2	_____ (skip to E1)	Date Frozen: ____/____/_____ M M D D Y Y Y Y

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

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

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SECTION E: 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 protease inhibitor tablets are needed. (Like all unused supplies, **unused protease inhibitor tablets should be returned to the CBL.**)

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 tablet(s) 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, complete the SM01 form and promptly freeze and store sample(s) at -70°C or lower. Batch samples and ship at least quarterly (include maximum of 36 cryovials per shipper). When shipper(s) is needed, complete “NIDDK Shipper Request Form” on CKiD website: [_http://www.statepi.jhsph.edu/ckid/admin/](http://www.statepi.jhsph.edu/ckid/admin/). Then, follow packaging instructions. **No Thursday/Friday shipments.**

When pickup has been scheduled, complete “Online Shipping Form” on CKiD website to notify the NIDDK BR 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	7 = Insufficient volume
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Sample Type (Required Volume in Top Color Tube Type):	(a) Sample Obtained:	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
	Yes No		
E1. Urine for NIDDK Biorepository (15.0 - 60.0 mL of urine in specimen container and transferred into collection cup with protease inhibitors)	1 2 (skip to c→)	_____ (skip to E2)	i. Was supernate decanted into urine transport cryovials? Yes.....1 No.....2 ii. Date Frozen: ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y

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IOHEXOL PROTOCOL

- E2. Is the participant completing iohexol study visit? Yes..... 1
No..... 2 → (End Form)

SECTION F: IOHEXOL STUDY PROTOCOL

INFUSION SYRINGE WEIGHT

- F1. **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.)

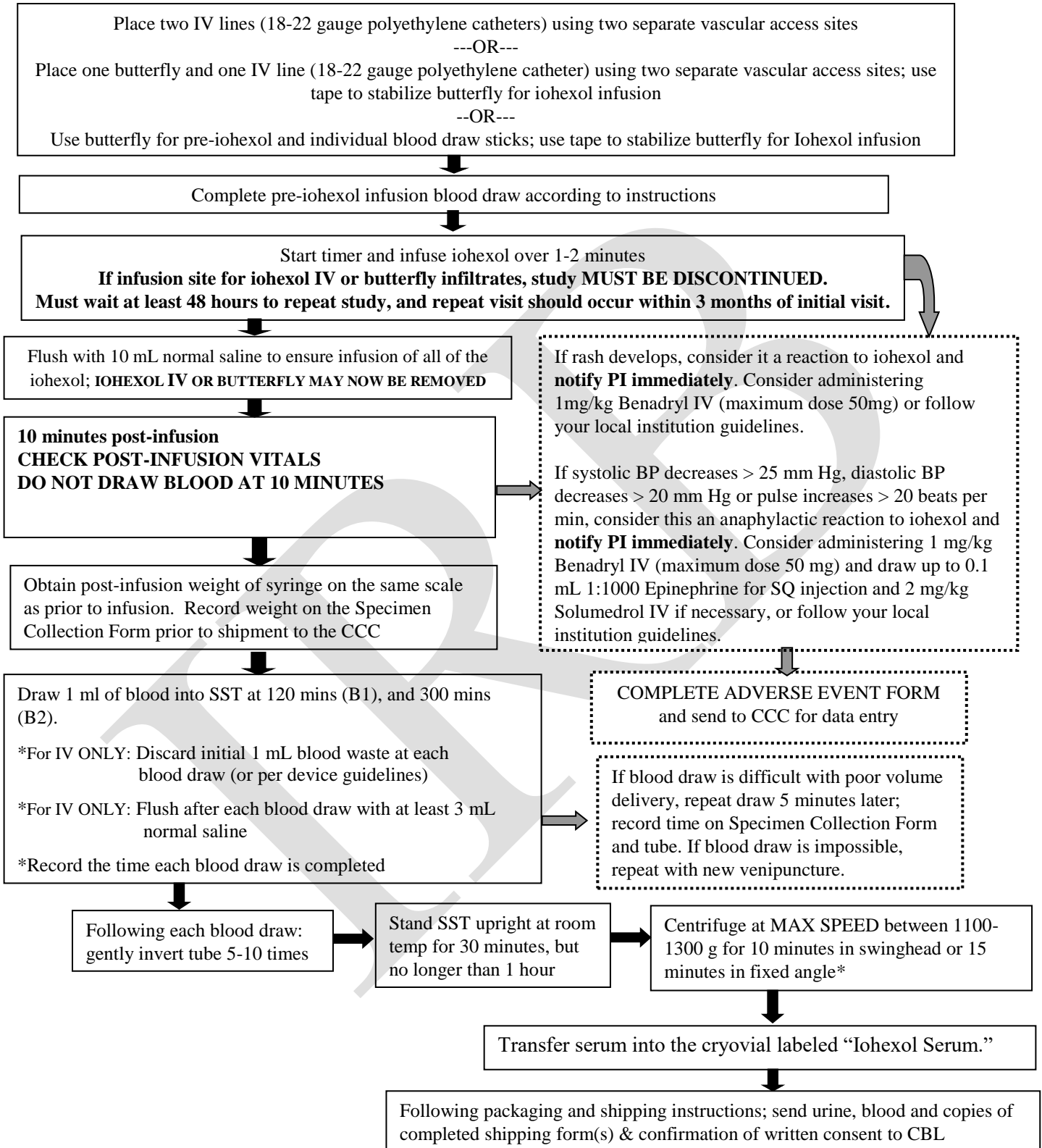
PRE AND POST SYRINGE WEIGHT MUST BE OBTAINED IN ORDER TO CALCULATE PARTICIPANT'S GFR.

IOHEXOL – Refer to Instructions for Iohexol Infusion and GFR Blood Draws Flow Chart on Page 10

- **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



**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

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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 (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:		
G2a.	Post- infusion blood pressure:	_____ / _____
b.	Post-infusion temperature:	_____ . _____ 1 = °C Typical range: 36.1 – 38.3 2 = °F Typical range: 94.5 – 100.6
c.	Post-infusion number of heart beats per minute:	_____
d.	Post-infusion respirations per minute:	_____

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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:		(iv) Blood Drawn via Venipuncture		(v) Blood Volume Collected (1 mL):	(vi) Centrifuged at Clinical Site:	
				Yes	No	Yes	No		Yes	No
G3a.	B1 2 hrs (120 min):	___ hr ___ mins	___ : ___ 1 = AM 2 = PM	1 (Skip to b)	2	1	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	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