

SPECIMEN COLLECTION FORM for Visit 5 (L51)

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 #: __ __

A3. FORM VERSION: 0 4 / 0 1 / 0 9a

A4. SPECIMEN COLLECTION DATE: __ __/ __ __/ __ __ __ __

M M D D Y Y Y Y

A5. FORM COMPLETED BY: __ __ __

(INITIALS)

A6. Is this study visit an irregular (accelerated) visit?	Yes.....	1
	No.....	2

The following sample should be collected.

<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

***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:

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

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

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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.

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



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: <u>Yes</u> <u>No</u>	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
B3. 1 st Morning Urine (Urine Creatinine, Urine Protein, Urine Albumin) (10.0 mL–14.5 mL in Light 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

SPECIMEN COLLECTION FORM for Visit V5 (L51)

SECTION C: Visit 5 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.

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

Collect **27.3-29.8 mL** if participant is < **30 kg** OR **31.3-33.8 mL** if participant is ≥ **30 kg**.

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

- If not collected at V1b and V3 - 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
- 3 mL into (1) PST 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

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

- If not collected at V1b and V3 - 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
- 5 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 If participant consented to **BIOLOGICAL** samples ONLY:

Collect **19.5-22.0 mL** if participant is < **30 kg** OR **23.5-26.0 mL** if participant is ≥ **30 kg**.

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

- 12.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR
- 3 mL into 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)**

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

- 14.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR
- 5 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 **21.3 – 23.8 mL** (regardless of weight):

Immediately transfer or draw:

- If not collected at V1b and V3 - 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 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 **13.5-16.0 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 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)**

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SECTION C: Visit 5 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 1100-1300g 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. 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.

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

iPTH/wrCRP
Pipette 0.75 mL of serum into a red-cryovial tube for CBL iPTH &, wrCRP

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.

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)"

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

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 Alicia Wentz that sample(s) have been shipped to 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).

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 -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:
<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 Alicia Wentz 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 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 Alicia Wentz 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>

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SECTION C: VISIT 5 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:	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
	Yes No		
C2. Renal/Iron Chemistries (6.0 mL in Tiger Top SST)	1 2 (skip to c→)	____ ____ (skip to C2a)	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
C2a. Cystatin C (1.0 mL in Tiger Top SST)	1 2 (skip to c→)	____ ____ (skip to C3)	Date Frozen: ____ / ____ / ____ M M D D Y Y Y Y
C3. Serum for iPTH, wrCRP & Vitamin D (2.5 mL of blood in Tiger Top SST)	1 2 (skip to c→)	____ ____ (skip to C4a)	Date Frozen: ____ / ____ / ____ M M D D Y Y Y Y
C4a. Local CBC (1.0 mL in Lavender Top tube)	1 2 (skip to C4b)	____ ____ (skip to C4b)	N/A
C4b. Local Renal Panel (3.0 mL in Local SST)	1 2 (skip to C5)	____ ____ (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.ihsph.edu/nephron/groups/aspproc/>, click on “Report Menu” and choose the appropriate lab report (i.e., Selected Renal Panel Lab Variables Report.)

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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:	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:																										
	<table style="width: 100%; border: none;"> <tr> <td style="text-align: center; width: 50%;"><u>Yes</u></td> <td style="text-align: center; width: 50%;"><u>No</u></td> </tr> </table>	<u>Yes</u>	<u>No</u>																										
<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)	<table style="width: 100%; border: none;"> <tr> <td style="text-align: center; width: 50%;">1</td> <td style="text-align: center; width: 50%;">2</td> </tr> <tr> <td colspan="2" style="text-align: center;">(skip to c→)</td> </tr> </table>	1	2	(skip to c→)		<table style="width: 100%; border: none;"> <tr> <td style="text-align: center; width: 50%;">— —</td> <td style="text-align: center; width: 50%;">— —</td> </tr> <tr> <td colspan="2" style="text-align: center;">(skip to C7)</td> </tr> </table>	— —	— —	(skip to C7)		Date Frozen: <table style="width: 100%; border: none;"> <tr> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">/</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">/</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> </tr> <tr> <td style="text-align: center;">M</td> <td style="text-align: center;">M</td> <td style="text-align: center;">D</td> <td style="text-align: center;">D</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">Y</td> </tr> </table>	—	—	/	—	—	/	—	—	—	—	M	M	D	D	Y	Y	Y	Y
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C7. Plasma for NIDDK Biosample Repository (**3.0 mL of blood (1) Green Top or **5.0 mL (2) Green Top PSTs)	<table style="width: 100%; border: none;"> <tr> <td style="text-align: center; width: 50%;">1</td> <td style="text-align: center; width: 50%;">2</td> </tr> <tr> <td colspan="2" style="text-align: center;">(skip to c→)</td> </tr> </table>	1	2	(skip to c→)		<table style="width: 100%; border: none;"> <tr> <td style="text-align: center; width: 50%;">— —</td> <td style="text-align: center; width: 50%;">— —</td> </tr> <tr> <td colspan="2" style="text-align: center;">(skip to D1)</td> </tr> </table>	— —	— —	(skip to D1)		Date Frozen: <table style="width: 100%; border: none;"> <tr> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">/</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">/</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> </tr> <tr> <td style="text-align: center;">M</td> <td style="text-align: center;">M</td> <td style="text-align: center;">D</td> <td style="text-align: center;">D</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">Y</td> </tr> </table>	—	—	/	—	—	/	—	—	—	—	M	M	D	D	Y	Y	Y	Y
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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 ≥ 30 kg

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SECTION D: Visit 5 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.**)

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 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) for 10 mins (swinghead units) – **OR** – 15 mins (fixed angle units).

Decant (pour off) the supernates (liquid reaction) into 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 cryovials per shipper.. When shipper(s) is needed, complete “*NIDDK Shipper Request Form*” on CKiD website: <http://www.statepi.jhsph.edu/ckid/admin/>.

When pickup has been scheduled, complete “*Online Shipping Form*” on CKiD website to notify Heather Higgins and Alicia Wentz 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: <small>Yes No</small>	(b) If No, specify reason <small>*SEE CODE LIST ABOVE</small>	(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)	<table style="margin: auto;"> <tr> <td style="text-align: center;">1</td> <td style="text-align: center;">2</td> </tr> <tr> <td colspan="2" style="text-align: center;">(skip to c→)</td> </tr> </table>	1	2	(skip to c→)		<p>— — —</p> <p>(skip to E1→)</p>	i. Was supernate decanted into urine transport cryovials? Yes.....1 No.....2 ii. Date Frozen: ___ ___ / ___ ___ / ___ ___ ___ ___ M M D D Y Y Y Y
1	2						
(skip to c→)							

SPECIMEN COLLECTION FORM for Visit V5 (L51)

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:		(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
	Yes	No		
E2. Whole Blood for Rutgers Cell & DNA Repository (7.8 mL of blood in 3 pediatric (2.6 mL) Yellow Top ACD tubes)	1	2 (skip to c→)	_____ (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

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

E3. Is this an irregular (accelerated) study visit?

Yes..... 1
 No..... 2 (END)

SPECIMEN COLLECTION FORM for Visit V5 (L51)

ONLY COMPLETE SECTIONS F & G IF THIS IS AN IRREGULAR STUDY VISIT.
For an accelerated study visit, additional blood should be collected for Iohexol-Based GFR.

**SECTION F: IRREGULAR STUDY 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, 240 & 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, and B3).**

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**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.
-

(i) Post Vitals:		
G2a.	Post- infusion blood pressure:	_____ / _____
b.	Post-infusion temperature:	_____ . ____ 1 = °C 2 = °F
c.	Post-infusion number of heart beats per minute:	_____
d.	Post-infusion respirations per minute:	_____

SPECIMEN COLLECTION FORM for Visit V5 (L51)

INVERT TUBE 5-10 TIMES AFTER EACH BLOOD DRAW

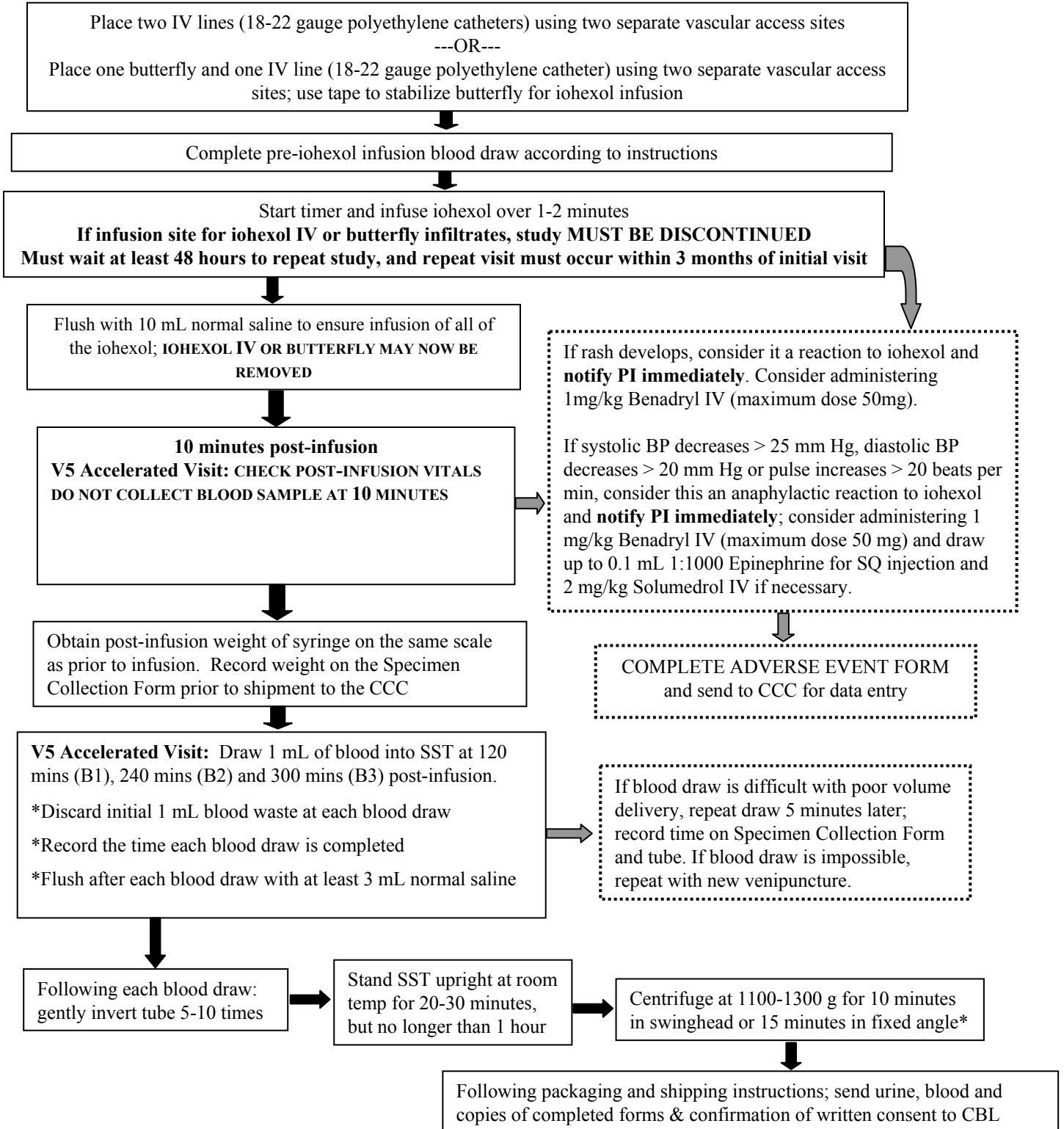
LET SST TUBE STAND 20-30 MINUTES (BUT NO LONGER THAN 1 HOUR)

CENTRIFUGE AT 1100-1300g (3000rpm with 10cm radius rotor) for 10 MINUTES IN SWING HEAD OR 15 MINUTES IN FIXED ANGLE

	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 Volume Collected (1 mL):	(v) Centrifuged at Clinical Site:	
				Yes	No		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	___ . ___ mL	1	2
G4a.	B2 4 hrs (240 min):	___ hr ___ mins	___ : ___ 1 = AM 2 = PM	1 (Skip to b)	2	___ . ___ mL	1 (Skip to G5a)	2 (Skip to G5a)
b.	B2 2nd attempt:	___ hr ___ mins	___ : ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2
G5a.	B3 5 hrs (300 min):	___ hr ___ mins	___ : ___ 1 = AM 2 = PM	1 (Skip to b)	2	___ . ___ mL	1 (END)	2 (END)
b.	B3 2nd attempt:	___ hr ___ mins	___ : ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2

SPECIMEN COLLECTION FORM for Visit 5 (L51)

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