

SPECIMEN COLLECTION FORM for Visit 1a (L01)

CKiD Chronic Kidney Disease in Children Cohort Study (CKiD)

SECTION A: GENERAL INFORMATION

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

|_| - |_|_| - |_|_|_|

A2. CKiD VISIT #: 0 1 a

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

A4. DATE OF VISIT: _____ / _____ / _____
M M D D Y Y Y Y

A5. FORM COMPLETED BY: _____
(INITIALS)

The following samples should be collected.

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

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SECTION B: PREGNANCY TEST AND FIRST 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 GFR TESTING DATE.

- 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
- B3. Is this study visit a Make-Up GFR visit?
- Yes..... 1 (See PROMPT Below)
- No..... 2 (Skip to B5)

MAKE-UP GFR VISIT PROMPT: COLLECT 1.0 mL OF BLOOD IN THE PROVIDED SST LABELED B0 BEFORE THE IOHEXOL INFUSION.

(Remember to waste 1cc if the blood was not collected from a butterfly.)

- B4. Indicate reason(s) for a Make-Up GFR visit: (Circle "Yes" or "No" for each):
- | | <u>Yes</u> | <u>No</u> |
|---|------------|----------------|
| IV infiltration..... | 1 | 2 |
| Inability to successfully draw 4 blood samples for iohexol..... | 1 | 2 |
| Other reason..... | 1 | 2 (Skip to E1) |
- Specify: _____ (Skip to E1)

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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 the central biochemistry laboratory.



Pour 5 to 14.5 mL of urine into 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:
B5. Urine Creatinine, Urine Protein (5.0 mL–14.5 mL in 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



Encourage fluids throughout the visit.



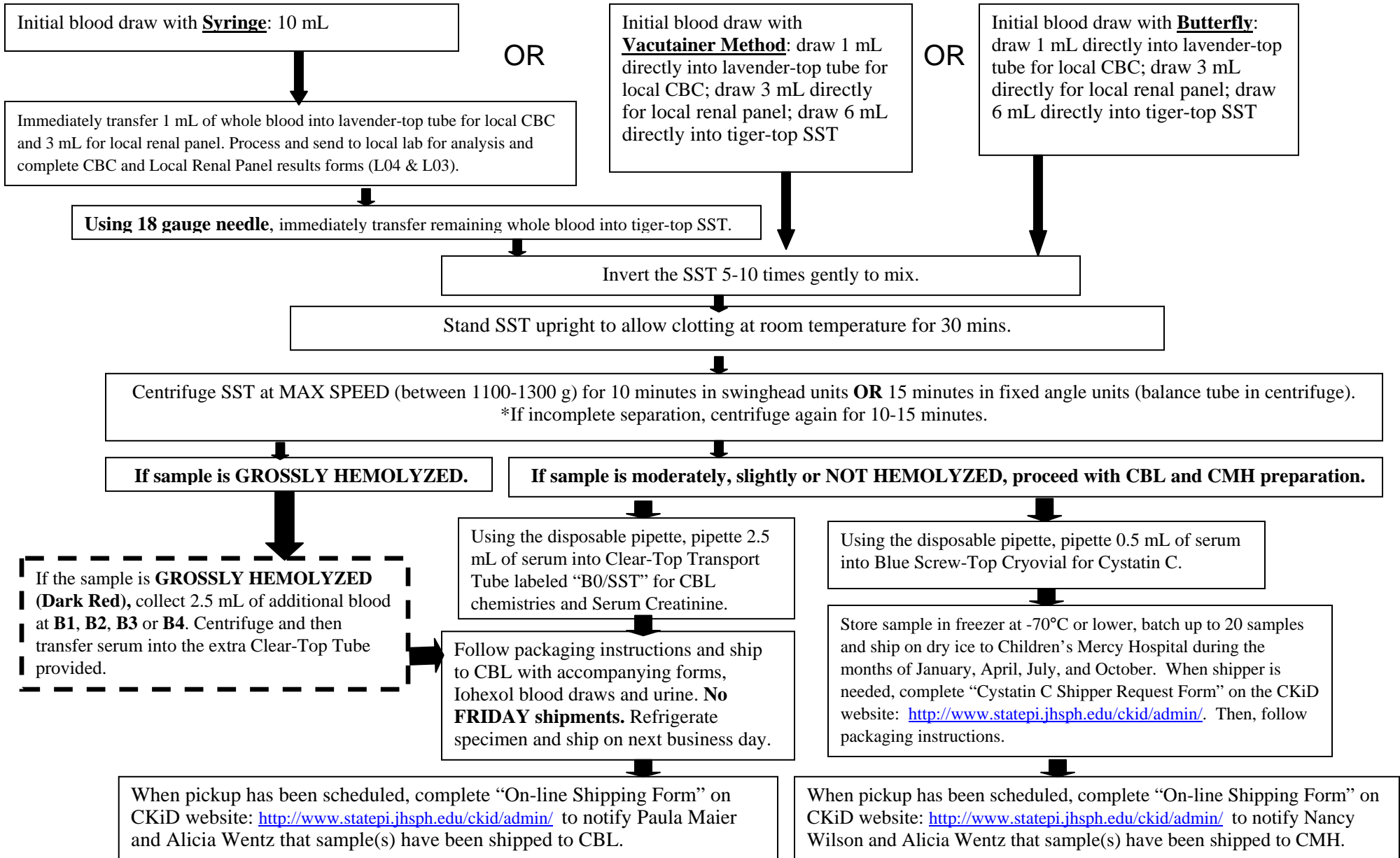
Place two IV lines (22 gauge polyethylene catheters); one in each arm
 --OR--
 Place one butterfly and one IV line (22 gauge polyethylene catheter); one in each arm;
 use tape to stabilize butterfly for Iohexol infusion



Complete Time=0 (Pre-Iohexol Infusion) blood draw according to MOP instructions/flowchart on page 3.
 NOTE: If patient has had a local CBC drawn within the past 30 days, those CBC results may be used instead of drawing another CBC and blood draw amounts can be decreased by 1 ml.

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SECTION C: PRE-IOHEXOL INFUSION (B0) BLOOD DRAW



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C1. ACTUAL TIME OF PRE-IOHEXOL INFUSION (B0) 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	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:
C2. Renal Chemistries (5.0 mL in Tiger Top SST)	1 2 (skip to c→)	_____ (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 (Clear).....4
C3. Cystatin C (1.0 mL in Tiger Top SST)	1 2 (skip to c→)	_____ (skip to C4)	Date Frozen: ____ / ____ / ____ M M D D Y Y Y Y
C4. Local CBC (1.0 mL in Lavender Top tube)	1 2 (skip to C5)	_____ (skip to C5)	N/A
C5. Local Renal Panel (3.0 mL in Local SST)	1 2 (skip to D2)	_____ (skip to D2)	N/A

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SECTION D: 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 1st morning 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: INFUSION SYRINGE WEIGHT

- E1. **SCALE MUST BE FIRST ZEROED BEFORE WEIGHING. REMOVE ALUMINUM FOIL PRIOR TO WEIGHING THE SYRINGE. THE SAME SCALE MUST BE USED TO WEIGH THE SYRINGE PRE AND POST IOXEHOL INFUSION.**
- a. Syringe Weight **Pre- Iohexol Infusion:** ____ . ____ (g)
- b. Syringe Weight **Post- Iohexol Infusion:** ____ . ____ (g) (Post-Infusion Weight should be **at least 6.0g** less than Pre-Infusion Weight. If Post-Infusion Weight is not at least 6g less, please confirm.)

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

SECTION F: IOHEXOL – Refer to Instructions for Iohexol Infusion and GFR Blood Draws Flow Chart on Page 8

- **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**

- F1. IOHEXOL INFUSION
- a. INFUSION START TIME: ____ : ____ 1 = AM 2 = PM

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- DO NOT DRAW BLOOD FROM THE IV SITE WHERE IOHEXOL WAS INFUSED. ANOTHER IV SITE MUST BE USED.
- COLLECT 1 mL of BLOOD FOR EACH IOHEXOL BLOOD DRAW AND TRANSFER INTO THE PROVIDED SST.
- RECORDING THE EXACT NUMBER OF MINUTES ON THE TIMER IS MORE IMPORTANT THAN DRAWING THE BLOOD EXACTLY AT 10, 30, 120 & 300 MINUTES AFTER IOHEXOL INFUSION. FOR EXAMPLE, IF BLOOD IS DRAWN AT 33 MINS INSTEAD OF 30 MINS, DOCUMENT BLOOD DRAWN @ 33 MINS.
- TIME SHOULD BE RECORDED IMMEDIATELY AFTER EACH BLOOD SAMPLE IS OBTAINED (i.e., B1, B2, B3, B4).

		(i) ACTUAL MINUTES on TIMER	(ii) ONLY if Timer malfunctions, record Clock Time using the same clock used for F1a	(iii) Difficult Blood Draw:		(iv) Blood Volume Collected (1 mL):	(v) Centrifuged at Clinical Site:	
				Yes	No		Yes	No
F2a.	B1 10 min:	___ minutes	___ : ___ 1 = AM 2 = PM	1 (Skip to b)	2	___ . ___ mL	1 (Skip to F3a)	2 (Skip to F3a)
b.	B1 2 nd attempt:	___ minutes	___ : ___ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2

**INVERT TUBE 5-10 TIMES AFTER EACH BLOOD DRAW
LET SST TUBE STAND 20-30 MINUTES (BUT NO LONGER THAN 1 HOUR)
CENTRIFUGE FOR AT LEAST 15 MINUTES AT 3000 RPM**

**POST VITALS SHOULD BE TAKEN IMMEDIATELY AFTER THE 10 MINUTE BLOOD DRAW
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.

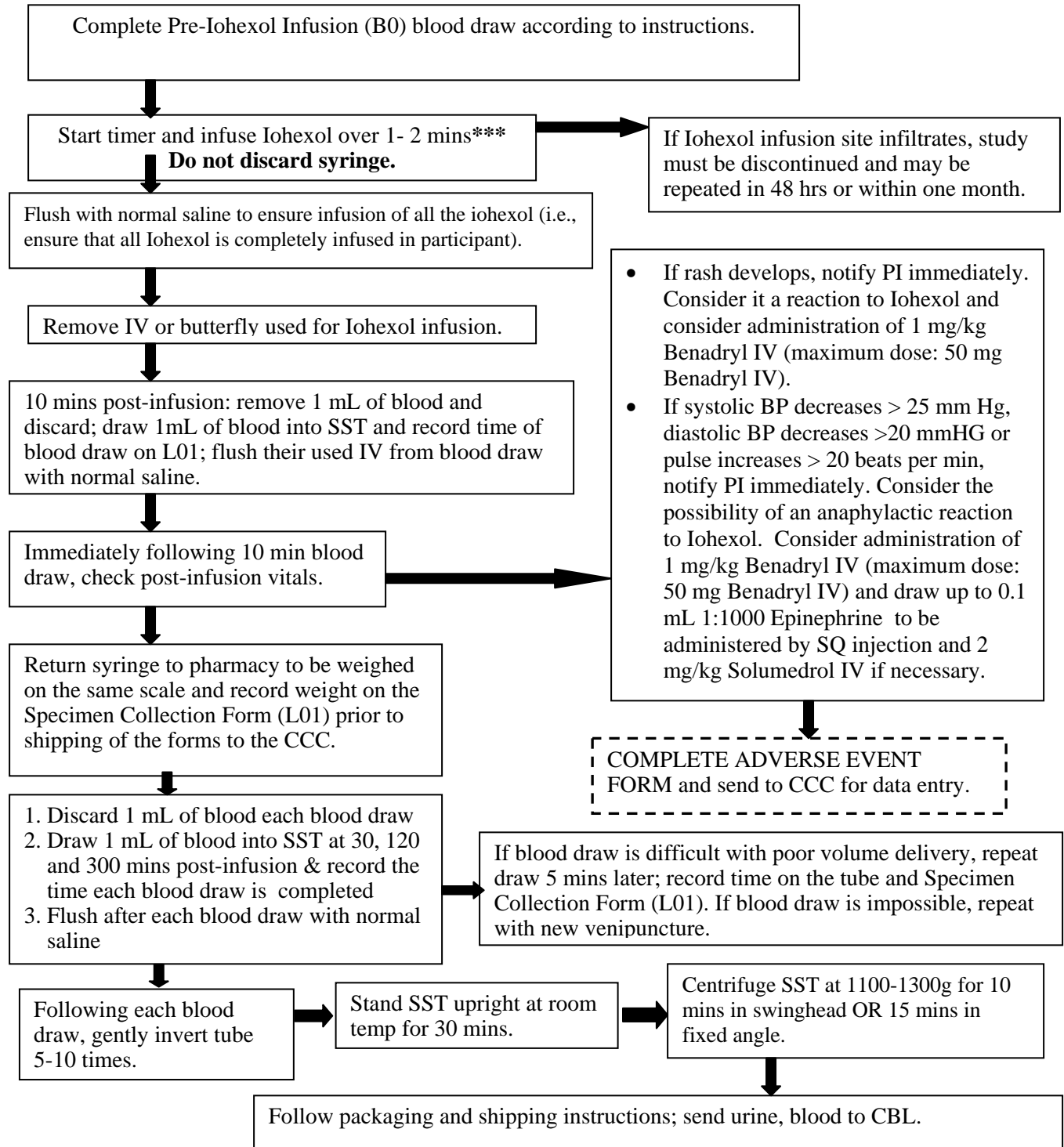
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(i) Post Vitals:		
F3a.	Post- infusion blood pressure:	_____ / _____
b.	Post-infusion temperature:	_____ . ____ 1 = °C 2 = °F
c.	Post-infusion number of heart beats per minute:	_____
d.	Post-infusion respirations per minute:	_____

		(i)	(ii)	(iii)		(iv)	(v)	
		ACTUAL MINUTES ON TIMER	ONLY if Timer malfunctions, record Clock Time using the same clock used for F1a	Difficult Blood Draw:	Yes	No	Blood Volume Collected (1 mL):	Centrifuged at Clinical Site:
							Yes	No
F4a.	B2 30 min:	___ ___ minutes	_____ : _____ 1 = AM 2 = PM	1 (Skip to b)	2	___ . ___ mL	1 (Skip to F5a)	2 (Skip to F5a)
	b. B2 2 nd attempt:	___ ___ minutes	_____ : _____ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2
F5a.	B3 120 min (2 hrs):	___ hr ___ ___ mins	_____ : _____ 1 = AM 2 = PM	1 (Skip to b)	2	___ . ___ mL	1 (Skip to F6a)	2 (Skip to F6a)
	b. B3 2 nd attempt:	___ hr ___ ___ mins	_____ : _____ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2
F6a.	B4 300 min (5 hrs):	___ hr ___ ___ mins	_____ : _____ 1 = AM 2 = PM	1 (Skip to b)	2	___ . ___ mL	1 (END)	2 (END)
	b. B4 2 nd attempt:	___ hr ___ ___ mins	_____ : _____ 1 = AM 2 = PM	1	2	___ . ___ mL	1	2

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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.**