

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: 1 0 / 0 1 / 1 2 a

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 | CBL | Batched (Ship in Jan, Apr, Jul or Oct) |
| Iohexol Blood | CBL | IMMEDIATELY |
| Urine | CBL | IMMEDIATELY |

**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 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 TRANSITIONAL (TRS01) FORM)

Negative..... 2

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C1. ACTUAL TIME OF PRE-IOHEXOL INFUSION 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: <u>Yes</u> <u>No</u> | (b) If No, specify reason *SEE CODE LIST ABOVE | (c) Additional Requirements: |
|---|---|--|---|
| C2. Renal/ Uric Acid Chemistries (2.0 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 (Yellow).....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 (1.5 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).

QUESTION D1 HAS BEEN DELETED.

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: 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.
- 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.

| (i) Post Vitals: | | |
|------------------|---|--|
| F2a. | Post- infusion blood pressure: | _____ / _____ |
| b. | Post-infusion temperature: | <div style="text-align: center;">_____ . ____</div> <div style="text-align: center;">1 = °C Typical range: 36.1 – 38.3</div> <div style="text-align: center;">2 = °F Typical range: 94.5 – 100.6</div> |
| c. | Post-infusion number of heart beats per minute: | _____ |
| d. | Post-infusion respirations per minute: | ___ ___ |

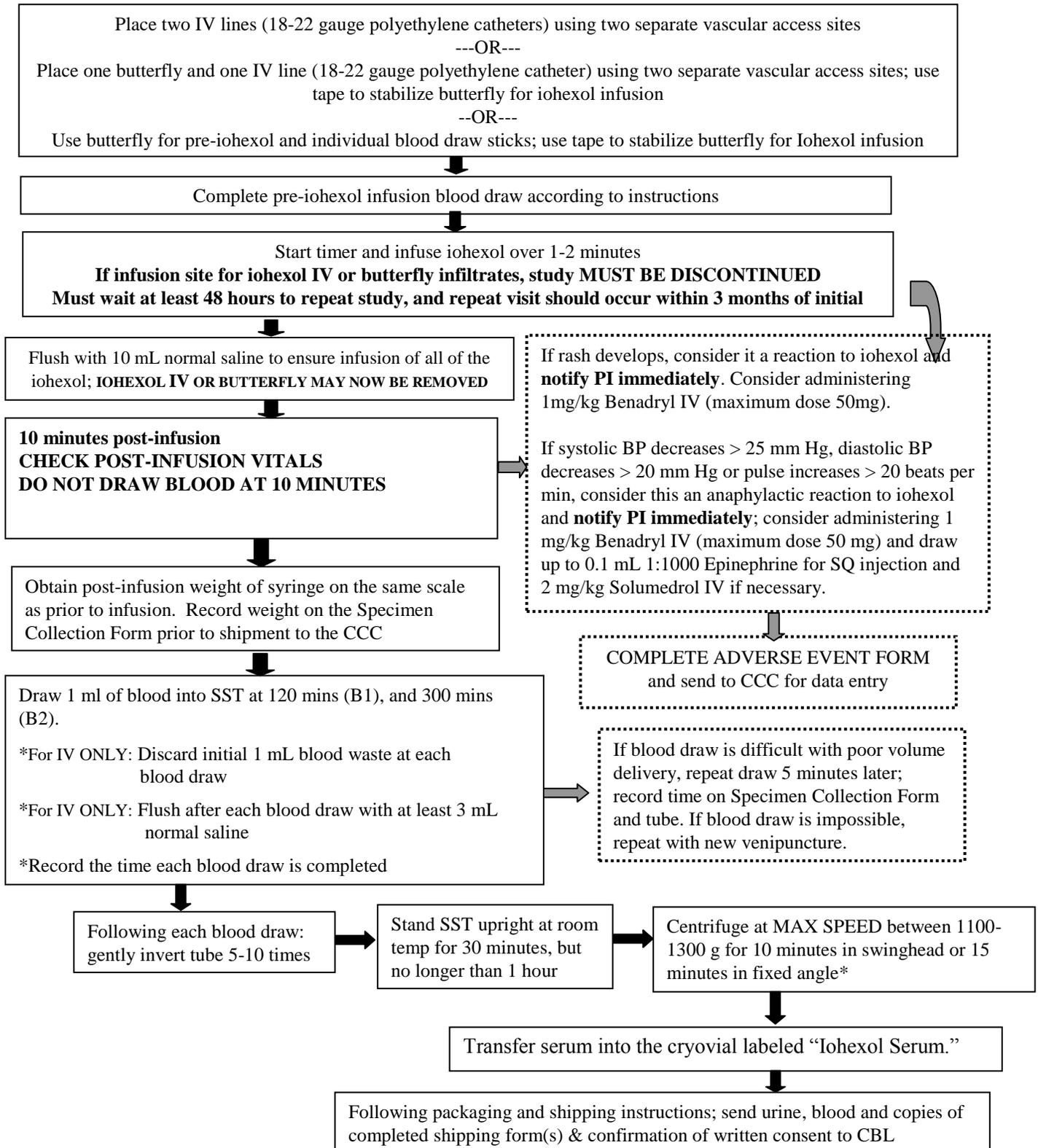
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INVERT TUBE 5-10 TIMES AFTER EACH BLOOD DRAW
LET SST TUBE STAND 30 MINUTES (BUT NO LONGER THAN 1 HOUR)
CENTRIFUGE AT MAX SPEED BETWEEN 1100-1300g (3000rpm with 10cm radius rotor) for 10 MINUTES IN SWING HEAD
OR 15 MINUTES IN FIXED ANGLE (BALANCE TUBES 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 |
| F3a. | B1 2 hrs (120 min): | ___ hr ___ mins | ___ : ___ 1 = AM 2 = PM | 1 (Skip to b) | 2 | 1 | 2 | ___ . ___ mL | 1 (Skip to F4a) | 2 (Skip to F4a) |
| b. | B1 2nd attempt: | ___ hr ___ mins | ___ : ___ 1 = AM 2 = PM | 1 | 2 | 1 | 2 | ___ . ___ mL | 1 | 2 |
| F4a. | 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 |

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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