

SPECIMEN COLLECTION FORM for Make-Up GFR Visits (MUGFR01)

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. Protocol type:

Regular Study Visit..... 0

Post-Transplant Visit..... 2

A3. CKiD VISIT #:

A4. FORM VERSION:

0 4 / 0 1 / 1 8a

A5. SPECIMEN COLLECTION DATE:

____ / ____ / ____
M M D D Y Y Y Y

A6. FORM COMPLETED BY (INITIALS):

The following samples should be collected.

Samples:

Serum

Iohexol Blood

Shipped to

CBL

CBL

Shipped:

IMMEDIATELY

IMMEDIATELY

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SECTION B: PREGNANCY TEST

- 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. 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 FORM)
Negative..... 2

B3. 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 all blood samples for Iohexol.....	1	2
Other reason.....	1	2 (Skip to C1)

Specify: _____ (Skip to C1)

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SECTION C: WEIGHT AND HEIGHT MEASUREMENTS

C1. Child Weight **(If weight is measured in pounds (lbs), please convert to kilograms (kg).)**

1 lb = (1/2.2) kg **Example: 150 lbs = 150/2.2 = 68.18 = 68.2 kg**

a. First Measurement: _____ . ____ **(kg)**

b. Second Measurement: _____ . ____ **(kg)**

i. Do the first and second measurements differ by more than 0.2 Kg?

Yes..... 1

No..... 2 **(Skip to C2)**

ii. Third Measurement: _____ . ____ **(kg)**

C2. Child Length/Height

a. Device used to obtain length/height **(Please circle the device used.)**

Measuring table with firm block and moveable footboard..... 1

Wall mounted stadiometer..... 2

b. First Measurement: _____ . ____ (cm)

c. Second Measurement: _____ . ____ (cm)

i. Do the first and second measurements differ by more than 0.3 cm?

Yes..... 1

No..... 2 **(Skip to C3)**

ii. Third Measurement: _____ . ____ (cm)

(i) Pre-Infusion Vitals:		
C3a.	Pre- infusion blood pressure:	_____ / _____
b.	Pre-infusion temperature:	_____ . ____ 1 = °C Typical range: 36.1 – 38.3 2 = °F Typical range: 94.5 – 100.6
c.	Pre-infusion number of heart beats per minute:	_____
d.	Pre-infusion respirations per minute:	_____

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SECTION D: PRE-IOHEXOL INFUSION BLOOD DRAW

Encourage fluids throughout the visit.

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
--OR--
Use butterfly for pre-iohexol and individual blood draw sticks; use tape to stabilize butterfly for Iohexol infusion

Collect 3mL of blood in SST and process blood according to MOP instructions/flowchart below.

PROCESSING OF PRE-IOHEXOL INFUSION BLOOD FOR CBL

Invert the 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 1100-1300 g (3000rpm with 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 for Pre-Iohexol level. Also, if the sample is **GROSSLY HEMOLYZED (Dark Red)**, collect 1 mL of additional blood at **B1 or B2**. Centrifuge and then transfer serum into the extra Orange Top Transport Tube provided.

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

B0

Using the disposable pipette, pipette 0.5 mL of serum into Round-bottom Orange Top Transport Tube labeled "B0" for B0 sample.

Follow packaging instructions and ship to CBL with accompanying forms, iohexol blood draws. **No FRIDAY shipments.** Refrigerate specimen and ship on next business day.

CBL Studies

Using the disposable pipette, pipette 0.5 mL of serum into Orange Top Transport Tube labeled "Serum CBL" for CBL studies.

Cystatin C

Using the disposable pipette, pipette 0.5 mL of serum into Blue Screw-Top Cryovial for Cystatin C. Store sample in freezer at -70°C or lower, batch up to 20 samples and ship on dry ice every four months to the CBL. When shipper is needed, complete "CBL 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.

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.

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D1. 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	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):	(a) Sample Obtained: Yes No	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
D2. Renal 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
D3. Cystatin C (1.0 mL in Tiger Top SST)	1 2 (skip to c→)	_____ (skip to E1)	Date Frozen: ____/____/____ M M D D Y Y Y Y

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 E: INFUSION SYRINGE WEIGHT

E1. **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 PARTICIPANT'S GFR.

SECTION F: IOHEXOL – Refer to Instructions for Iohexol Infusion and GFR Blood Draws Flow Chart on Page 6

- **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 for Make-up GFRs

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

--OR--

Use butterfly for pre-iohexol and individual blood draw sticks; use tape to stabilize butterfly for Iohexol infusion

Complete pre-iohexol infusion blood draw according to instructions

Start timer and infuse iohexol 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

Flush with 10 mL normal saline to ensure infusion of all of the iohexol; IOHEXOL IV OR BUTTERFLY MAY NOW BE REMOVED

10 minutes post-infusion
CHECK POST-INFUSION VITALS
DO NOT DRAW BLOOD AT 10 MINUTES

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

Draw 1 ml of blood into SST at 120 mins (B1), and 300 mins (B2).

* For IV ONLY: Discard initial 1 mL blood waste at each blood draw (or per device guidelines)

* For IV ONLY: Flush after each blood draw with at least 3 mL normal saline

*Record the time each blood draw is completed

Following each blood draw:
gently invert tube 5-10 times

Stand SST upright at room temp for 30 minutes, but no longer than 1 hour

Centrifuge at MAX SPEED between 1100-1300 g for 10 minutes in swinghead or 15 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

If rash develops, consider it a reaction to iohexol and **notify PI immediately**. Consider administering 1mg/kg Benadryl IV (maximum dose 50mg) or follow your local institution guidelines.

If systolic BP decreases > 25 mm Hg, diastolic BP decreases > 20 mm Hg or pulse increases > 20 beats per 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, or follow your local institution guidelines.

COMPLETE ADVERSE EVENT FORM and send to CCC for data entry

If blood draw is difficult with poor volume delivery, repeat draw 5 minutes later; record time on Specimen Collection Form and tube. If blood draw is impossible, repeat with new venipuncture.

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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F1. IOHEXOL INFUSION

a. INFUSION START TIME: _____ : _____ 1 = AM 2 = PM

FOLLOW PROCEDURES FOR COMPLETING GFR PROTOCOL

- 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 (for 2-point GFR protocol).**
- **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.

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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) 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:		
F2a.	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 F1a	(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 – 2 hrs (120 min)::	___ 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 – 5 hrs (300 min):	___ hr ___ mins	___ : ___ 1 = AM 2 = PM	1	2	1	2	___ . ___ mL	1	2