SPECIMEN COLLECTION FORM for EVEN Follow-up Visits 4, 6, 8, … (L41)

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 8 / 0 1 / 1 6

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

A5. FORM COMPLETED BY (INITIALS): ___ ___ ___

The following samples should be collected.

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

*** COLLECT IOHEXOL BLOOD DRAW: Only if Cohort 3 participants who consent to iohexol protocol or Cohorts 1 & 2 participants had previous iGFR>90**

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

Samples:	Shipped to:	Shipped:
Serum (Biological)	**NIDDK Biosample Repository**	**Batched (Ship in Jan, Apr, Jul or Oct)**
Plasma (Biological)	**NIDDK Biosample Repository**	**Batched (Ship in Jan, Apr, Jul or Oct)**
Urine (Biological)	**NIDDK Biosample Repository**	**Batched (Ship in Jan, Apr, Jul or Oct)**
Toenail Clippings (Biological)	**NIDDK Biosample Repository**	**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 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 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).

(Refer to MOP Section 11 and/or CBL flowchart for additional information and directions)

Pour at least1mL 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:** Yes	No	**(b) If No, specify reason *SEE CODE LIST ABOVE**	**(c) Additional Requirements:**
B3. Urine Creatinine, Urine Protein, Urine Albumin (CBL) (1 mL–10 mL)	1 **(skip to c→)**	2	___ ___ **(skip to C1)**	i. Is this a first morning urine sample? Yes.....1 No.....2
				ii. Time of Collection: __ __ : __ __ 1 = am, 2 = pm

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SECTION C: Visit 4 BLOOD DRAW

For Initial Blood Draw with Syringe, Vacutainer OR Butterfly Method:
Select the Type of Consent Obtained (options 1 through 3) That Pertains to the CKiD Participant:

1 **If participant consented to BIOLOGICAL samples:**
Collect **14-15** mL if participant is < **30 kg** **OR** **20-21** mL if participant is ≥ **30 kg**.

If < **30 kg**, immediately transfer **(using 18 gauge needle)** or draw:
- 8.5 mL into (2) Tiger-Top SSTs for CBL & NIDDK BR
- 3 mL into (1) PST for NIDDK Biosample Repository
- 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:
- 12.5 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)*
- 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 **5-6** mL from all participants (regardless of weight) as specified below.

Immediately transfer (using 18 gauge needle) or draw:
- 2.5 mL into (1) Tiger-Top SSTs for CBL
- 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)***

3 **For Participant Completing Iohexol Study Visit**
Only Cohort 3 participants who consent to iohexol protocol or Cohorts 1 & 2 participants with previous iGFR>90

For IOHEXOL study visits:
- ***1mL of additional blood into Tiger Top SST for CBL Iohexol Blank (B0) blood sample***

Iohexol is infused at the time of initial blood draw.
Refer to page 10 for **Instructions for Iohexol Infusion and GFR Blood Draws.**

PROCESSING OF BLOOD FOR CBL & NIDDK BR

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 1100-1300 g (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 VISITS ONLY:
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 lipid. 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.

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: 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.

NIDDK BR

Pipette 3 mL (<30kg) or 5 mL (≥ 30kg) of serum into clear top cryovial & 1.5 (<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)."* Store samples in freezer at -70°C or lower, & batch up to 40 samples and ship on dry ice in January, April, July or October to the NIDDK BR. 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: http://www.statepi.jhsph.edu/ckid/admin/ 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; 2 = Difficult Blood Draw; 3 = Participant Refused; 4 = Red Blood Cell Contamination; 5 = Inadvertently Destroyed; 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/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*

*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://statepiaps6.jhsph.edu/nephron/groups/aspproc/**, click on "Report Menu" and choose the appropriate lab report (i.e., Selected Renal Panel Lab Variables Report.)

C6. Did the participant consent to have biological samples (i.e., serum, plasma and urine samples) stored at the NIDDK Biosample Repository?

Yes..... 1

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

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:**
C7. Serum for NIDDK Biosample Repository (**6.0 mL or **10.0 mL of blood in Tiger Top SST)	1 **(skip to c→)**	2	___ ___ **(skip to C8)**	Date Frozen: ___ ___ /___ ___ /___ ___ ___ ___ M M D D Y Y Y Y
C8. Plasma for NIDDK Biosample Repository (***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 D1)**	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 D: 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 (PI) 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 PI tablets should be returned to the CBL**.)

TABLE A:

Urine Volume	# of PI 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, promptly freeze and store sample(s) at -70ºC 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/. Then, follow packaging instructions.

When pickup has been scheduled, complete *"Online Shipping Form"* on CKiD website to notify Heather Higgins, Sandra Ke 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

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:**
D1.	Urine for NIDDK Biosample Repository (15.0 - 60.0 mL of urine in specimen container and transferred into collection cup with protease inhibitors)	1 **(skip to c→)**	2	___ ___ **(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

SECTION E: 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).

E2. 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

IOHEXOL PROTOCOL

E3. Is the participant completing iohexol study visit? Yes..... 1
No..... 2 → **(Skip to Section H)**

ONLY COMPLETE SECTIONS F & G IF PARTICIPANT IS COMPLETING IOHEXOL STUDY VISIT.

Only Cohort 3 participants who consent to iohexol protocol or Cohorts 1 & 2 participants with previous iGFR>90 should complete iohexol protocol. If you have additional questions, contact CCC.
For an iohexol study visit, additional blood (including blood for the Iohexol "B0" Blank sample) should be collected for Iohexol-Based GFR.

SECTION F: 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 PARTICIPANT'S GFR.

SECTION G: 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 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

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

→ 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.

↓

COMPLETE ADVERSE EVENT FORM and send to CCC for data entry

↓

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

→ 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.

↓

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

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

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).**
- **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 = ºC Typical range: **36.1 – 38.3** 2 = ºF 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: Yes No**	**(iv) Blood Drawn via Venipuncture Yes No**	**(v) Blood Volume Collected (1 mL):**	**(vi) Centrifuged at Clinical Site: 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 **(Skip to H1a)** 2 **(Skip to H1a)**
b.	**B2** 2nd attempt:	___ **hr** ___ ___ mins	__ __ : __ __ 1 = AM 2 = PM	1 2	1 2	___ . ___ mL	1 2

TOENAIL CLIPPINGS FOR THE REPOSITORY SHOULD BE SHIPPED ONLY IF THE SAMPLE WAS NOT COLLECTED AT V4

SECTION H:

H1 a. Is this a study Visit 4? Yes..... 1 **(skip to H1c)**
No..... 2

b. Were toenail clippings collected at Visit 4? Yes..... 1 **(END; if toenail clippings collected at V4 do not collect at V6)**
No..... 2

c. Did the participant consent to have biological samples (i.e., nail clippings) stored at NIDDK Biosample Repository?
Yes..... 1
No..... 2 **(END)**

TOENAIL CLIPPING COLLECTION

- **The collection of TOENAILS is preferred. DO NOT** collect fingernail clippings. Also DO NOT collect toenails if participant has nail fungus, or discoloration causing pain or discomfort.

- STAINLESS STEEL NAIL CLIPPERS MUST BE USED TO COLLECT NAIL CLIPPINGS. Use small (pediatric size) stainless steel nail clippers (see Figure A) for younger participants and large stainless steel nail clippers (see Figure B) for older children. Both sizes are included in the CKiD starter package.

- Clean the blades of the nail clippers with **SaniZide Plus** prior to use (provided by the CBL).
- Whenever possible, the Study Coordinator should clip all (10) toenails, removing approximately 1 millimeter from each nail (See Figure C). **Be prepared to collect flyaway nails.**
- (To use nail clippers, see Figures A – D). Refer to CKiD MOP Section 12 for further details.
- Carefully place the nail clippings into the cryovial (see Figure D). After using the nail clipper,
- spray the clipper with **SaniZide Plus** and wipe with clean cloth.

ALTHOUGH PICTURES DEPICT THE CLIPPING OF FINGERNAILS, AT VISIT 4 TOENAIL CLIPPINGS ARE PREFERRED.

Figure A

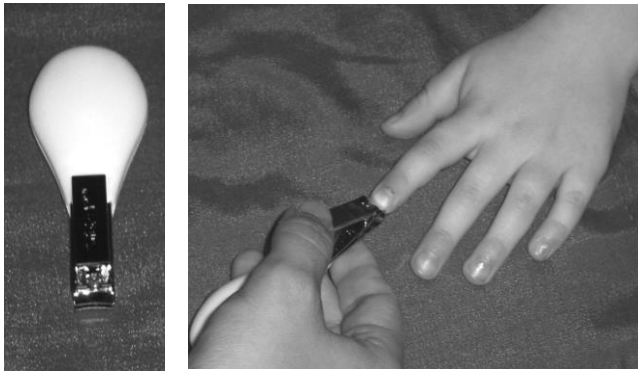


Figure B

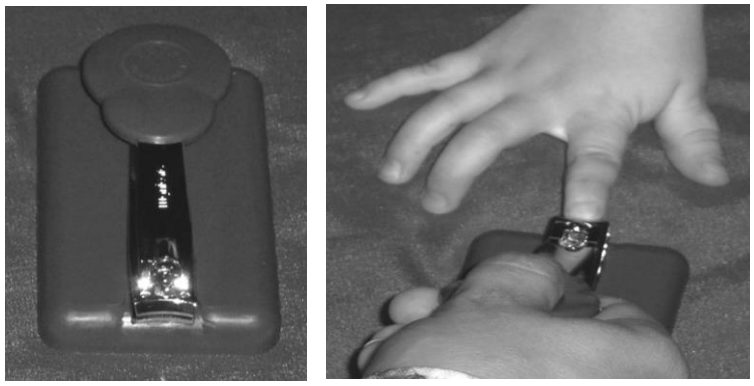
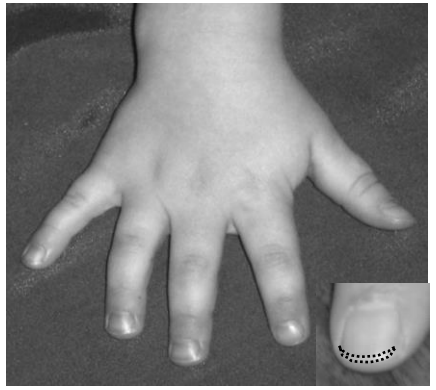


Figure C



Provide 10 nail clippings that are at least 1 mm tall

Figure D

H2. Were 10 toenail clippings collected?

Yes..... 1 **(END)**

No..... 2

a. How many toenail clippings were collected?

___ ___

b. Specify reason "10" toenail clippings were not collected: (e.g., Nail fungus or discoloration causing pain or discomfort)

Nail fungus or discoloration..... 1 **(END)**

Nails not long enough..... 2 **(END)**

Participant Refused..... -7 **(END)**

Other..... 3

i. Specify: _____

_____