

SPECIMEN COLLECTION FORM for Visit 1b (L02)

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 #: 0 1 b

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

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

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

The following sample should be collected.

<u>Samples:</u> Serum	<u>Shipped to:</u> CBL	<u>Shipped:</u> BATCHED (Ship in Jan, Apr, Jul or Oct)
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Please refer to questions 25 and 26 on the Eligibility Form to determine if genetic and/or 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>
Whole Blood (Genetic)	Rutgers Repository	IMMEDIATELY
Nail Clippings (Biological)	NIDDK Biosample Repository	IMMEDIATELY
Hair (Biological)	NIDDK Biosample Repository	IMMEDIATELY
Serum (Biological)	NIDDK Biosample Repository	Batched (Jan, Apr, Jul or Oct)
Plasma (Biological)	NIDDK Biosample Repository	Batched (Jan, Apr, Jul or Oct)
Urine (Biological)	NIDDK Biosample Repository	Batched (Jan, Apr, Jul or Oct)

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SECTION B: Visit 1B BLOOD DRAW

For Initial Blood Draw with Syringe, Vacutainer OR Butterfly Method:
Select the Type of Consent Obtained (options 1 through 4) That Pertain to the CKiD Participant:

1 If participant consented to both BIOLOGICAL AND GENETIC samples:

Collect 15.3-17.8 mL if participant is < 30 kg **OR** 19.3-21.8 mL if participant is ≥ 30 kg.

If < 30 kg, immediately transfer or draw:

- 7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository (ACD Tubes must be COMPLETELY FILLED TO THE TOP)
- 4.5 mL into (1) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 3 mL into (1) PST for NIDDK Biosample Repository
- 2.5 mL of additional blood in SST for CBL (if initial sample is grossly hemolyzed)

If ≥ 30 kg, immediately transfer or draw:

- 7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository (ACD Tubes must be COMPLETELY FILLED TO THE TOP)
- 6.5 mL into (1) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 5 mL into two (2) PSTs for NIDDK Biosample Repository
- 2.5 mL of additional blood in SST for CBL (if initial sample is grossly hemolyzed)

2 If participant consented to BIOLOGICAL samples ONLY:

Collect 7.5-10.0 mL if participant is < 30 kg **OR** 11.5-14.5 mL if participant is ≥ 30 kg.

If < 30 kg, immediately transfer or draw:

- 4.5 mL into (1) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 3 mL into (1) PST for NIDDK Biosample Repository
- 2.5 mL of additional blood in SST for CBL (if initial sample is grossly hemolyzed)

If ≥ 30 kg, immediately transfer or draw:

- 6.5 mL into (1) Tiger-Top SST for CBL and NIDDK Biosample Repository
- 5 mL into two (2) PSTs for NIDDK Biosample Repository
- 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 9.3-11.8 mL from all participants (regardless of weight)

Immediately transfer or draw:

- 7.8 mL into (3) 2.6mL ACD tubes for Rutgers Genetic Repository (ACD Tubes must be COMPLETELY FILLED TO THE TOP)
- 1.5 mL into (1) Tiger-Top SST for CBL
- 2.5 mL of additional blood in SST for CBL (if initial sample is grossly hemolyzed)

4 If participant did NOT consent to BIOLOGICAL AND GENETIC samples:

- Collect 1.5-4.0 mL from all participants (regardless of weight). Immediately transfer or draw 1.5 mL into (1) Tiger-Top SST for CBL.
- 2.5 mL of additional blood in SST for CBL (if initial sample is grossly hemolyzed)

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SECTION B: Visit 1B BLOOD DRAW PROCESSING

PROCESSING BLOOD FOR CBL, NIDDK BR AND RUTGER SAMPLES

CBL & NIDDK BR (Serum)

Invert the Tiger Top SST 5-10 times gently to mix.

Stand SST upright to allow clotting at room temperature for 30 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.

If the sample is **GROSSLY HEMOLYZED (Dark Red)**, then collect 2.5 mL of additional blood in a SST for. Centrifuge and then transfer serum into the extra Clear-Top Tube provided.

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

Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) serum into clear top cryovial.

Store sample in freezer at -70°C or lower, batch up to 40 samples and ship during **January, April, July and October**. 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.

Pipette 0.5 mL of serum into a red-top transport tube for CBL chemistries (iPTH & wrCRP).

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 "iPTH/wrCRP Dry Ice 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 Paula Maier and Alicia Wentz that sample(s) have been shipped to CBL.

NIDDK BR (Plasma)

Invert each PST 5-10 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.

Store sample in freezer at -70°C or lower, batch up to 40 samples and ship during the months of **January, April, July and October**. 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 B: Visit 1B BLOOD DRAW AND PROCESSING

B1. 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: <u>Yes</u> <u>No</u> 1 2 (skip to c→)	(b) If No, specify reason *SEE CODE LIST ABOVE ____	(c) Additional Requirements:
B2. Serum for iPTH & wrCRP (1.5 mL of blood in Tiger Top SST)			Date Frozen: ____ / ____ / ____ ____ ____ M M D D Y Y Y Y

B3. Did the participant consent to have whole blood stored at Rutgers, the Genetic Repository?
 Yes..... 1
 No..... 2 (Skip to B5)

Sample Type (Required Volume in Top Color Tube Type):	(a) Sample Obtained: <u>Yes</u> <u>No</u> 1 2 (skip to c→)	(b) If No, specify reason *SEE CODE LIST ABOVE ____ (skip to B5)	(c) Additional Requirements:
B4. Whole Blood for Rutgers Cell & DNA Repository (7.8 mL of blood in 3 pediatric (2.6 mL) Yellow Top ACD tubes)		Deleted ii. Time of Collection	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.

SITES CAN OBTAIN RESULTS FOR LAB VALUES THAT HAVE BEEN IDENTIFIED AS “KEY VARIABLES”. TO OBTAIN RESULTS, GO TO THE CKiD NEPHRON WEBSITE: <https://statepiaps.jhsph.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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B5. Did the participant consent to have biological samples (i.e., serum, plasma, urine, nail clippings and hair samples) stored at NIDDK Biosample Repository?

Yes..... 1

No..... 2 (END)

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:																												
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B6. 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 B7)</td> </tr> </table>	— —	— —	(skip to B7)		Date Frozen: <table style="width: 100%; border: none;"> <tr> <td style="width: 25%;">—</td> <td style="width: 25%;">—</td> <td style="width: 25%;">/</td> <td style="width: 25%;">—</td> <td style="width: 25%;">—</td> <td style="width: 25%;">/</td> <td style="width: 25%;">—</td> <td style="width: 25%;">—</td> <td style="width: 25%;">—</td> <td style="width: 25%;">—</td> </tr> <tr> <td style="text-align: center;">M</td> <td style="text-align: center;">M</td> <td></td> <td style="text-align: center;">D</td> <td style="text-align: center;">D</td> <td></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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B7. 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 C1)</td> </tr> </table>	— —	— —	(skip to C1)		Date Frozen: <table style="width: 100%; border: none;"> <tr> <td style="width: 25%;">—</td> <td style="width: 25%;">—</td> <td style="width: 25%;">/</td> <td style="width: 25%;">—</td> <td style="width: 25%;">—</td> <td style="width: 25%;">/</td> <td style="width: 25%;">—</td> <td style="width: 25%;">—</td> <td style="width: 25%;">—</td> <td style="width: 25%;">—</td> </tr> <tr> <td style="text-align: center;">M</td> <td style="text-align: center;">M</td> <td></td> <td style="text-align: center;">D</td> <td style="text-align: center;">D</td> <td></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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** Collect 3.0 mL of whole blood for children < 30 kg and 5.0 mL for children ≥ 30 kg

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SECTION C: Visit 1B 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 clear top cap, pour urine into tube and SNAP 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 transport tube, promptly freeze and store sample(s) at -70°C or lower. Batch up to 36 samples. When shipper is needed, complete “NIDDK Shipper Request Form” on CKiD website: <http://www.statepi.ihsp.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 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
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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:
C1. Urine for NIDDK Biosample Repository (15.0 - 60.0 mL of urine in specimen container and transferred into collection cup with protease inhibitors)	1 2 (skip to c→)	_____ (skip to D1)	i. Was supernate decanted into urine transport cryovials? Yes.....1 No.....2 ii. Date Frozen: ____ / ____ / ____ <div style="text-align: center; font-size: small;">M M D D Y Y Y Y</div>

SPECIMEN COLLECTION FORM for Visit 1b (L02)

SECTION D: NAIL CLIPPING COLLECTION

- Collection of fingernails is preferred. **DO NOT** collect fingernail clippings if the participant has acrylic nails. If the participant cannot provide fingernail clippings, the Study Coordinator may clip the participant's toenails instead. **FINGERNAILS AND TOENAILS SHOULD NOT BE COLLECTED IN THE SAME CRYOVIAL** (collect one or the other).
- **STAINLESS STEEL NAIL CLIPPERS MUST BE USED TO COLLECT NAIL CLIPPINGS.** Use small (pediatric size) stainless steel nail clippers (see Figure A) for younger children 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 **Simple Green D** prior to use (provided in 1st V1b ambient kit sent from the CBL).
- Whenever possible, the Study Coordinator should clip all (10) fingernails, 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, soak the clipper in **Simple Green D**.



Figure C

Figure A

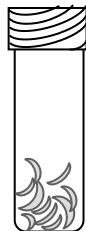


Figure B



Provide 10 nail clippings that are at least 1 mm tall

Figure D



SPECIMEN COLLECTION FORM for Visit 1b (L02)

D1. Does the participant have acrylic nails?

- Yes..... 1 (**Skip to D3**)
- No..... 2

D2. Were 10 fingernail clippings collected?

- Yes..... 1 (**Skip to E1**)
- No..... 2

a. How many fingernail clippings were collected?

___ ___

b. Specify reason "10" fingernail clippings were not collected.

- Nails not long enough..... 1 (**Skip to D3**)
- Participant Refused..... -7 (**Skip to D3**)
- Other..... 2

i. Specify: _____

D3. Were 10 toenail clippings collected?

- Yes..... 1 (**Skip to E1**)
- 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 (**Skip to E1**)
- Nails not long enough..... 2 (**Skip to E1**)
- Participant Refused..... -7 (**Skip to E1**)
- Other..... 3

i. Specify: _____

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SECTION E: HAIR SAMPLE COLLECTION

- STAINLESS STEEL SCISSORS MUST BE USED TO COLLECT HAIR SAMPLE. The scissors are included in the CKiD starter package.
- DO NOT collect hair sample if the participant has colored, straightened or chemically altered hair
- Clean blades of stainless steel scissors with **Simple Green D** prior to use.
- Use powder-free gloves.
- Refer to CKiD MOP Section 12 for further details.
 - Lift up the top layer of hair from the **occipital** region of the scalp (see Figure A). Isolate a small thatch of hair (at least 20 fibers) from this region (see Figure B).
 - **Place the label with the participant's KID ID # tightly around all 20 strands of hair located at the distal end (furthest from the scalp)** (see Figure C).
 - Cut the hair sample off the participant's head **as close to the scalp as possible** (see Figure D).
 - Place cut thatch of hair inside aluminum foil (4 X 4) and fold the top of the foil to completely enclose the hair sample.
 - Place the aluminum foil inside a Ziplock bag (4 X 4) with the gel desiccant pellets in it and seal.
 - Store sample at room temperature in a dark place prior to shipment.
 - After using the scissors, soak in **Simple Green D**.



Figure A



Occipital Region of Scalp

Figure B



Figure C



Place the KID ID label tightly around all 20 strands.

Figure D



Cut the hair sample off the participant's head as close to the scalp as possible.

SPECIMEN COLLECTION FORM for Visit 1b (L02)

E1. Does the participant have permed, dyed, colored, straightened or chemically altered hair?

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

No..... 2

E2. Was the Study Coordinator able to cut at least 20 fibers of hair from the **occipital** region?

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

No..... 2

a. Specify reason "20" hair fibers were not collected:

Hair not long enough..... 1 **(END)**

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

Other..... 2

i. Specify: _____
