

# 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 8 / 0 1 / 2 1

A4. SPECIMEN COLLECTION DATE:

\_\_\_ / \_\_\_ / \_\_\_  
M M D D Y Y Y Y

A5. FORM COMPLETED BY (INITIALS):

\_\_\_

The following sample should be collected.

Samples:

Serum

Shipped to:

CBL

Shipped:

BATCHED (Ship in Jan, Apr, Jul or Oct)

Plasma

CBL

BATCHED (Ship in Jan, Apr, Jul or Oct)

Please refer to questions 26 and 27 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:

Samples:

Whole Blood (Genetic)

Shipped to:

NIDDK Biorepository

Shipped:

IMMEDIATELY

Serum (Biological)

NIDDK Biorepository

Batched (Jan, Apr, Jul or Oct)

Plasma (Biological)

NIDDK Biorepository

Batched (Jan, Apr, Jul or Oct)

Urine (Biological)

NIDDK Biorepository

Batched (Jan, Apr, Jul or Oct)

**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 six (6) months.  
For specific questions, contact your CCC prior to shipment.**

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## SECTION B: Visit V1B BLOOD DRAW

For Initial Blood Draw with Syringe, Vacutainer OR Butterfly Method:

Select the type of consent obtained (options 1 through 4) that pertains to the CKiD Participant:

**1**

**If participant consented to both BIOLOGICAL AND GENETIC samples:**

Collect 15 mL if participant is < 30 kg **OR** 19 mL if participant is ≥ 30 kg.

If < 30 kg, immediately transfer (using 18 gauge needle) or draw:

- 6 mL into (1) 6mL ACD tubes for Genetic sample (ACD Tube must be COMPLETELY FILLED)
- 5 mL into (1) Tiger-Top SST for CBL and NIDDK Biorepository
- 4 mL into two (2) PSTs for CBL and NIDDK Biorepository

If ≥ 30 kg, immediately transfer (using 18 gauge needle) or draw:

- 6 mL into (1) 6mL ACD tubes for Genetic sample (ACD Tube must be COMPLETELY FILLED)
- 7 mL into (1) Tiger-Top SST for CBL and NIDDK Biorepository
- 6 mL into two (2) PSTs for CBL and NIDDK Biorepository

**2**

**If participant consented to BIOLOGICAL samples ONLY:**

Collect 9 mL if participant is < 30 kg **OR** 13 mL if participant is ≥ 30 kg.

If < 30 kg, immediately transfer or draw:

- 5 mL into (1) Tiger-Top SST for CBL and NIDDK Biorepository
- 4 mL into two (2) PSTs for and CBL NIDDK Biorepository

If ≥ 30 kg, immediately transfer or draw:

- 7 mL into (1) Tiger-Top SST for CBL and NIDDK Biorepository
- 6 mL into two (2) PSTs for CBL and NIDDK Biorepository

**3**

**If participant consented to GENETIC samples ONLY:**

Collect 9 mL from all participants (regardless of weight)

Immediately transfer or draw:

- 6 mL into (1) 6mL ACD tube for Genetic sample (ACD Tubes must be COMPLETELY FILLED)
- 2 mL into (1) Tiger-Top SST for CBL
- 1 mL into (1) PST for CBL

**4**

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

Collect 3 mL from all participants (regardless of weight). Immediately transfer or draw 2 mL into (1) Tiger-Top SST for CBL and 1mL into PST for CBL.

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## SECTION B: Visit 1B BLOOD DRAW PROCESSING PROCESSING BLOOD FOR CBL AND NIDDK BR SAMPLES

### CBL & NIDDK BR (Serum)

Invert the Tiger Top 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 1100-1300g (3000rpm with 10cm radius rotor) for 10 mins in swinghead OR 15 mins in fixed angle. \*If incomplete separation, centrifuge again 10-15 mins.

#### NIDDK (Serum)

Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) serum into clear top cryovial (use different pipettes for serum and plasma). \*If there is any extra serum, then pipette the extra serum into the clear top cryovial marked "NIDDK BR SERUM".

Complete the SM01 form, store sample(s) in freezer at -70°C or lower, batch up to 40 samples and ship during **January, April, July and October. No Thursday/Friday shipments.** When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: <https://statepi.jhsph.edu/ckid/coordinator-resources/>. Then, follow packaging instructions.

#### iPTH/hsCRP

Pipette 0.5 mL of serum into red top cryovial tube for CBL iPTH & hsCRP

#### Vitamin D

Pipette 0.5 mL of serum into red top cryovial for CBL Vitamin D

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 "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. Refrigerate and ship on next business day.

### CBL & NIDDK BR (Plasma)

Invert each PST 8-10 times gently to mix.

Centrifuge each PST at MAX SPEED between 1100-1300g for 10 mins (swinghead) OR 15 mins (fixed angle).

#### FGF-23

Pipette 0.5 mL of plasma into a cryovial with a green cap insert for CBL FGF-23

Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) plasma into cryovial with green cap insert (use different pipettes for serum and plasma). \*If there is any extra plasma, then pipette the extra plasma into the green cap insert cryovial marked "PLASMA (Extra)".

Complete the SM01 form, store sample(s) in freezer at -70°C or lower, batch up to 40 samples and ship during the months of **January, April, July and October. No Thursday/Friday shipments.** When shipper is needed, complete "NIDDK BR Shipper Request Form" on the CKiD website: <https://statepi.jhsph.edu/ckid/coordinator-resources/>. Then, follow packaging instructions.

### NIDDK BR (Whole Blood for DNA)

Invert ACD Tube 6 times gently to mix blood with additives.

Keep tube at room temperature. **DO NOT FREEZE.**

Follow packaging instructions, complete DNA Collection Form and ship immediately to NIDDK Biorepository with accompanying forms. **Specimen can be shipped on Friday.**

Complete "On-line Shipping Form" on CKiD website to notify KIDMAC that sample(s) have been shipped.

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 and the NIDDK BR.

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## SECTION B: Visit 1B BLOOD DRAW AND PROCESSING

B1. ACTUAL TIME OF BLOOD DRAW \_\_\_\_\_ : \_\_\_\_\_ 1 = AM 2 = PM

<b>Reasons Code List*</b>	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 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:
B2a. Serum for iPTH, hsCRP & Vitamin D (2.0 mL of blood in Tiger Top SST)	1 (skip to c→)      2	_____ (skip to B2b)	Date Frozen: ____/____/_____ M M D D Y Y Y Y
B2b. Plasma for FGF-23 (1.0 mL of blood in PST)	1 (skip to c→)      2	_____ (skip to B3)	Date Frozen: ____/____/_____ M M D D Y Y Y Y

B3. Did the participant consent to have whole blood stored at NIDDK Biorepository?  
 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>	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
B4. Whole Blood for NIDDK Biorepository (6 mL of blood in 1 (6 mL) ACD tube)	1 (skip to c→)      2	_____ (skip to B5)	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

## SPECIMEN COLLECTION FORM for Visit 1b (L02)

B5. Did the participant consent to have biological samples (i.e., serum, plasma, and urine) stored at NIDDK Biorepository?

Yes..... 1

No..... 2 **(END)**

<b>Reasons Code List*</b>	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 in Top Color Tube Type):	(a) Sample Obtained:	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
	<u>Yes</u> <u>No</u>		
B6. Serum for NIDDK Biorepository (**3.0 mL or **5.0 mL of blood in Tiger Top SST)	1                  2 (skip to c→)	_____ (skip to B7)	Date Frozen: _____/_____/_____ M M D D Y Y Y Y
B7. Plasma for NIDDK Biorepository (**3.0 mL of blood (1) Green Top or **5.0 mL (2) Green Top PSTs)	1                  2 (skip to c→)	_____ (skip to C1)	Date Frozen: _____/_____/_____ M M D D Y Y Y Y

\*\* Collect 3.0 mL of whole blood for participants < 30 kg and 5.0 mL for participants ≥ 30 kg

## SPECIMEN COLLECTION FORM for Visit 1b (L02)

### 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 90 mL 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 protease inhibitor tablets are needed. (Like all unused supplies, **unused protease inhibitor tablets should be returned to the CBL.**)

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, complete the SM01 form and promptly freeze and store sample(s) at -70°C 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: <https://statepi.jhsph.edu/ckid/coordinator-resources/>. Then, follow packaging instructions. **No Thursday/Friday shipments.**

When pickup has been scheduled, complete "Online Shipping Form" on CKiD website to notify the NIDDK 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    7 = Insufficient volume

Sample Type (Required Volume in Top Color Tube Type):	(a) Sample Obtained:	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
	Yes      No		
C1. Urine for NIDDK Biorepository (15.0 - 60.0 mL of urine in specimen container and transferred into collection cup with protease inhibitors)	1      2 (skip to c→)	__ __ (END FORM)	i. Was supernate decanted into urine transport cryovials? Yes.....1 No.....2  ii. Date Frozen: ___ / ___ / ___ <div style="text-align: center; margin-left: 100px;"> <span style="margin: 0 10px;">M</span> <span style="margin: 0 10px;">M</span> <span style="margin: 0 10px;">D</span> <span style="margin: 0 10px;">D</span> <span style="margin: 0 10px;">Y</span> <span style="margin: 0 10px;">Y</span> <span style="margin: 0 10px;">Y</span> <span style="margin: 0 10px;">Y</span> </div>

Urine Volume	# of Protease Inhibitor Tablets
10 – 15 mL	1
16 – 30 mL	2
31 – 45 mL	3
46 – 60 mL	4