

# SPECIMEN COLLECTION FORM for ODD Follow-up Visits (3, 5, 7...) (L31)

## 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 3 / 0 1 / 1 8a

A4. SPECIMEN COLLECTION DATE:

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

A5. FORM COMPLETED BY (INITIALS):

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The following sample 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)
Plasma	CBL	BATCHED (Ship in Jan, Apr, Jul or Oct)
Urine	CBL	IMMEDIATELY

Please refer to questions 27 on the Eligibility Form to determine if 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>
<i>Serum (Biological)</i>	<i>NIDDK Biorepository</i>	BATCHED (Ship in Jan, Apr, Jul or Oct)
<i>Plasma (Biological)</i>	<i>NIDDK Biorepository</i>	BATCHED (Ship in Jan, Apr, Jul or Oct)
<i>Urine (Biological)</i>	<i>NIDDK Biorepository</i>	BATCHED (Ship in Jan, Apr, Jul or Oct)
<i>*Whole Blood (Genetic)</i>	<i>NIDDK Biorepository</i>	IMMEDIATELY

\*ONLY collect whole blood for NIDDK Biorepository, if sample was not collected at V1b OR if sample collected at V1b was inadequate.

**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.**



## SECTION C: Visit 3 BLOOD DRAW

For Initial Blood Draw with **Syringe, Vacutainer OR Butterfly Method**: Select the type of consent obtained (options 1 through 4):  
**ONLY collect whole blood for NIDDK Biorepository, if sample was not collected at V1b or sample collected at V1b was inadequate.**

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

Collect **22.5-23.5 mL** if participant is **< 30 kg** **OR** **28.5-29.5 mL** if participant is **≥ 30 kg**.

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

- If not collected at V1b - 6 mL into (1) 6mL ACD tube for Genetic sample (ACD Tube must be **COMPLETELY FILLED**)
- 10 mL into (2) Tiger-Top SST for CBL and NIDDK Biorepository
- 4 mL into two (2) PSTs for CBL and NIDDK Biorepository
- 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:

- If not collected at V1b - 6 mL into (1) 6mL ACD tube for Genetic sample (ACD Tube must be **COMPLETELY FILLED**)
- 14 mL into (2) Tiger-Top SST for CBL and NIDDK Biorepository
- 6 mL into two (2) PSTs for NIDDK Biorepository
- 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 consented to **BIOLOGICAL** samples ONLY:

Collect **16.5-17.5 mL** if participant is **< 30 kg** **OR** **22.5-23.5 mL** if participant is **≥ 30 kg**.

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

- 10 mL into (2) Tiger-Top SSTs for CBL & NIDDK Biorepository
- 4 mL into one (1) PSTs for CBL and NIDDK Biorepository
- 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:

- 14 mL into (2) Tiger-Top SSTs for CBL & NIDDK Biorepository
- 6 mL into (2) PST for NIDDK Biorepository
- 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 If participant consented to **GENETIC** samples ONLY, collect **13.5-14.5 mL** from all participants (regardless of weight):

Immediately transfer or draw:

- If not collected at V1b - 6 mL into (1) 6mL ACD tube for Genetic sample (ACD Tube must be **COMPLETELY FILLED**)
- 4mL into (1) Tiger-Top SST for CBL
- 1 mL into PST 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)*

### 4 If participant did NOT consent to **BIOLOGICAL** samples and Genetic samples:

Collect **7.5-8.5 mL** from all participants (regardless of weight) as specified below.

Immediately transfer (using 18 gauge needle) or draw:

- 4 mL into (1) Tiger-Top SSTs for CBL
- 1 mL into PST 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)*

## SECTION C: Visit 3 BLOOD DRAW PROCESSING

### 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.

You must send hemolyzed sample to CBL. Also if the sample is **GROSSLY HEMOLYZED (Dark Red)**, then 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.**

#### NIDDK (Serum)

Pipette 3mL (<30kg) or 5mL (≥30kg) serum into clear top cryovial for NIDDK BR (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"*

#### iPTH/hsCRP

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

#### Vitamin D

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

#### Cystatin C

Using the disposable pipette, pipette 0.5 mL of serum into Blue Screw-Top Cryovial for Cystatin C.

#### FGF-23

Pipette 0.5 mL of plasma into a cryovial with 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)".*

#### CBL Studies

Using the disposable pipette, pipette 0.5 of serum into Orange Top Transport Tube labeled "Serum CBL" for CBL renal/uric acid). Follow packaging instructions and ship to CBL with accompanying forms and urine. **No FRIDAY shipments.** Refrigerate specimen and ship on next business day.

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

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.** Ship on next business day.

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

### CBL & NIDDK BR (Plasma)

Invert each PST 8-10 times gently to mix.

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

### NIDDK BR (Whole Blood for DNA)

Invert the 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**

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.

## SECTION C: Visit 3 BLOOD DRAW AND PROCESSING

C1. ACTUAL TIME OF BLOOD DRAW \_\_\_\_\_ : \_\_\_\_\_ 1 = AM 2 = PM

<b>Reasons Code List*</b>	1 = Not required 2 = Difficult Blood Draw 3 = Participant Refused	4 = Red Blood Cell Contamination 5 = Inadvertently Destroyed 6 = Oversight	7 = Exceed maximum allowable volume
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Sample Type (Required Volume in Top Color Tube Type):	(a) Sample Obtained: <small>Yes                  No</small>	(b) If No, specify reason <small>*SEE CODE LIST ABOVE</small>	(c) Additional Requirements:
C2a. Renal/Uric Acid Chemistries (1.0 mL in Tiger Top SST)	1                  2 (skip to c→)	_____ (skip to C2b)	<b>Indicate the appearance of the serum after centrifuging.</b> Grossly (Dark Red).....1 Moderately (Red/Light Red).....2 Slightly (Pink).....3 Not Hemolyzed (Yellow).....4
C2b. Cystatin C (1.0 mL in Tiger Top SST)	1                  2 (skip to c→)	_____ (skip to C3)	Date Frozen: ____ / ____ / ____ M M D D Y Y Y Y
C3a. Serum for iPTH, hsCRP & Vitamin D (2.0 mL of blood in Tiger Top SST)	1                  2 (skip to c→)	_____ (skip to C3b)	Date Frozen: ____ / ____ / ____ M M D D Y Y Y Y
C3b. Plasma for FGF-23 (1.0 mL of blood in PST)	1                  2 (skip to c→)	_____ (skip to C4a)	Date Frozen: ____ / ____ / ____ M M D D Y Y Y Y
C4a. Local CBC (1.0 mL in Lavender Top tube)	1                  2 (skip to C4b)	_____ (skip to C4b)	<b>N/A</b>
C4b. Local Renal Panel (1.5 mL in Local SST)	1                  2 (skip to C5)	_____ (skip to C5)	<b>N/A</b>

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.)

C5. Did the participant consent to have biological samples (i.e., serum, plasma and urine) stored at NIDDK Biorepository?

Yes..... 1

No..... 2 (Skip to E1)

<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:
	Yes	No		
C6. Serum for NIDDK Biorepository (**6.0 mL or **10.0 mL of blood in Tiger Top SST)	1 <b>(skip to c→)</b>	2	_____ <b>(skip to C7)</b>	Date Frozen: ____/____/____ M M D D Y Y Y Y
C7. Plasma for NIDDK Biorepository (***3.0 mL of blood (1) Green Top or ***5.0 mL (2) Green Top PSTs)	1 <b>(skip to c→)</b>	2	_____ <b>(skip to D1)</b>	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



