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

### **CKiD Chronic Kidney Disease in Children Cohort Study SECTION A: GENERAL INFORMATION**

PARTICIPANT ID: AFFIX ID LABEL OR ENTER NUMBER IF ID LABEL IS NOT AVAILABLE				
CKiD VISIT #:				
FORM VERSION:	<u>0 3 / 0 1 / 1 8a</u>			
SPECIMEN COLLECTION DATE:	$\overline{M} \overline{M} \overline{D} \overline{D} \overline{V} \overline{Y} \overline{Y} \overline{Y} \overline{Y}$			
FORM COMPLETED BY (INITIALS):				
	CKID VISIT #: FORM VERSION: SPECIMEN COLLECTION DATE:			

The following sample should be collected.

Samples:	Shipped to:	Shipped:
Serum	CBL	IMMEDIATELY
Serum	CBL	BATCHED (Ship in Jan, Apr, Jul or Oct)

**Plasma CBL BATCHED** (Ship in Jan, Apr, Jul or Oct)

**CBL** Urine **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:

Samples:	Shipped to:	<u>Shipped:</u>
Serum (Biological)	<b>NIDDK Biorepository</b>	<b>BATCHED</b>

(Ship in Jan, Apr, Jul or Oct)

Plasma (Biological) **NIDDK Biorepository BATCHED** 

(Ship in Jan, Apr, Jul or Oct)

Urine (Biological) **BATCHED NIDDK Biorepository** 

(Ship in Jan, Apr, Jul or Oct)

\*Whole Blood (Genetic) NIDDK Biorepository **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.

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

#### SECTION B: PREGNANCY TEST AND FIRST MORNING URINE COLLECTION

B1.	ls p	participant a female of child	-bearing potential?		
		S	•	•	
		: QUESTION B2 IS FOR F REGNANCY TEST DATE I			
B2.	a.	Urine pregnancy test date	:/	$-\frac{1}{D}$	
	b.	Urine pregnancy results: Positive Negative	1 (END; COI		
		FIRS	MORNING UI	RINE COLLECTI	ION
				ontainer that was shipped to collect FRESH urine samp	to the family before the visit.  ble during CKiD visit.
		Pou	ar at least 1 mL of uring	e into the CBL transpor	t tube.
C	heck	that all information is corre	ect on the urine collecti	ion tube and follow pac	kaging instructions and ship to CBL.
ns Cod	e List	t*: 1= Not required 2 = Difficult Urine Co 3 = Participant Refus	ollection 5 = In	ollection Contamination advertently Destroyed versight	7 = Insufficient Volume
		Sample Type (Required Volume):	(a) Sample Obtained: <u>Yes</u> <u>No</u>	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
B3.	Urii	ne Creatinine, Urine Protein, ne Albumin (CBL) mL-10 mL)	1 2 (skip to c→)	(skip to C1)	i. Is this a first morning urine sample? Yes1 No2 ii. Time of Collection:
1					1 4 6

#### **SECTION C: Visit 3 BLOOD DRAW**

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

## 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  $\ge 30 \text{ kg}$ .

#### 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 $\geq 30$ 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  $\ge 30 \text{ kg}$ .

## 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 $\geq 30$ 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) NIDDK BR CBL & NIDDK BR (Plasma)** (Whole Blood for DNA) Invert the Tiger Top SST 5 times gently to mix. Invert each PST 8-10 times gently to mix. Invert the ACD Tube 6 times gently Stand SST upright to allow clotting at room temperature for 30 mins and not more than 1 hour (60 mins). to mix blood with additives. Centrifuge each PST at 1100-Centrifuge SST at MAX SPEED between 1100-1300g (3000rpm with 10cm radius rotor) for 10 mins in 1300g for 10 mins (swinghead) swinghead OR 15 mins in fixed angle. \*If incomplete separation, centrifuge again 10-15 mins. Keep tube at room temperature. **OR** 15 mins (fixed angle). DO NOT FREEZE. You must send If sample is moderately, slightly or NOT HEMOLYZED, proceed hemolyzed sample to Follow packaging CBL. Also if the sample with CBL and NIDDK BR preparation. is GROSSLY instructions, HEMOLYZED (Dark Pipette 1.5mL (<30kg) or complete DNA FGF-23 Red), then collect 1 mL NIDDK (Serum) 2.5mL (≥30kg) plasma into **Cystatin C** Collection Form and Pipette of additional blood in a iPTH/hsCRP Vitamin D Pipette 3mL (<30kg) or Using the SST. Centrifuge and then cryovial with green cap insert Pipette 0.5 ship immediately to Pipette 0.5 $0.5 \, \text{mL of}$ 5mL (≥30kg) serum into transfer serum into the disposable mL of serum mL of serum (use different pipettes for **NIDDK** plasma extra Orange Top clear top cryovial for into a red top pipette, into a red top serum and plasma). Biorepository with Transport Tube provided. NIDDK BR (use different into a pipette 0.5 mL cryovial tube cryovial for \*If there is any extra plasma, accompanying pipettes for serum and for CBL iPTH of serum into cryovial CBL &. hsCRP Blue Screwthen pipette the extra plasma into plasma). forms. **Specimen** with Vitamin D Top Cryovial \*If there is any extra serum. **CBL Studies** the green cap insert cryovial can be shipped on green cap then pipette the extra serum for Cystatin Using the disposable marked "PLASMA (Extra)". insert for into the clear top cryovial C. pipette, pipette 0.5 of serum CBL marked "NIDDK BR SERUM" into Orange Top Transport Tube labeled "Serum CBL" FGF-23 Complete "On-line for CBL renal/uric acid). Complete the SM01 form, store Shipping Form" on CKiD sample in freezer at -70°C or lower, Complete the SM01 form, store Follow packaging website to notify KIDMAC Store sample in freezer at -70°C or lower and batch up to batch up to 40 samples and ship on instructions and ship to sample in freezer at -70°C or lower. 20 samples and ship quarterly during the months of dry ice quarterly (Jan, April, July and that sample(s) have been batch up to 40 samples and ship on CBL with accompanying Oct) to the NIDDK BR. No January, April, July and October. When shipper is forms and urine. No dry ice quarterly (Jan. April, July shipped. Thursday/Friday shipments. When needed, complete "CBL Dry Ice Shipper Request Form" FRIDAY shipments. and Oct) to the NIDDK BR. No shipper is needed, complete "NIDDK on the CKiD website: Thursday/Friday shipments. Refrigerate specimen and BR Dry Ice Shipper Request Form" https://statepi.jhsph.edu/ckid/coordinator-resources ship on next business day. When shipper is needed, complete on CKiD website:

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.

Ship on next business day.

"NIDDK BR Dry Ice Shipper

Request Form" on CKiD website:

https://statepi.jhsph.edu/ckid/coordinator-

Then, follow packaging instructions.

Then, follow packaging instructions and ship to CBL

with accompanying forms. No FRIDAY shipments.

https://statepi.jhsph.edu/ckid/coordinator-

Then, follow packaging instructions.

resources

## **SECTION C: Visit 3 BLOOD DRAW AND PROCESSING**

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

Reasons Code List\*: 1= Not required 4 = Red Blood Cell Contamination 7 = Exceed maximum allowable volume 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:
C2a.	Renal/Uric Acid Chemistries (1.0 mL in Tiger Top SST)	1 2 (skip to c→)	(skip to C2b)	Indicate the appearance of the serum after centrifuging.  Grossly (Dark Red)
C2b.	Cystatin C (1.0 mL in Tiger Top SST)	1 2 (skip to c→)	(skip to C3)	Date Frozen:/
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://
C3b.	Plasma for FGF-23 (1.0 mL of blood in PST)	1 2 (skip to c→)	(skip to C4a)	Date Frozen: //
C4a.	Local CBC (1.0 mL in Lavender Top tube)	1 (skip to C4b)	(skip to C4b)	N/A
C4b.	Local Renal Panel (1.5 mL in Local SST)	1 2 (skip to C5)	(skip to C5)	N/A

Sites can obtain results for lab values that have been identified as "KEY VARIABLES". To obtain results, go the CKiD Nephron Website: <a href="https://statepiaps8.jhsph.edu/nephron/groups/aspproc/">https://statepiaps8.jhsph.edu/nephron/groups/aspproc/</a>, 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)

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 in Top Color Tube Type):	(a) Sample Ob <u>Yes</u>	tained:	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
C6.	Serum for NIDDK Biorepository (**6.0 mL or **10.0 mL of blood in Tiger Top SST)	1 (skip to c→)	2	(skip to C7)	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 (skip to c→)	2	(skip to D1)	Date Frozen:  M M D D Y Y Y Y

<sup>\*\*</sup> Collect 6.0 mL of whole blood for participants < 30 kg and 10.0 mL for participants  $\ge$  30 kg

<sup>\*\*\*</sup> Collect 3.0 mL of whole blood for participants < 30 kg and 5.0 mL for participants  $\ge$  30 kg

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### SECTION D: Visit 3 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.

Urine Volume
10 − 15 mL
16 − 30 mL
31 − 45 mL
46 − 60 mL

4 of Protease
Inhibitor Tablets
2
3
4
4
4
4
4
4

TABLE A:

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 BR and KIDMAC that sample(s) have been shipped to NIDDK BR.

Reasons Code List\*: 1= Not 2 = Difficult Urine 3 = Participant 4 = Collection 5 = Inadvertently 6 = Oversight 7 = Insufficient required Collection Refused Contamination Destroyed volume

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:
D1. 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→)	 (skip to D2→)	i. Was supernate decanted into urine transport cryovials? Yes1 No2 ii. Date Frozen: / /

#### OPTIONAL 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).

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Yes 1	→ Complete Local Urine Assay Results Form L06, ONLY if local labs ar
No 2	CLINICALLY INDICATED

D2. Was a urine protein to creatinine ratio assay performed at the clinical site's local laboratory?

## SECTION E: WHOLE BLOOD FOR NIDDK BIOREPOSITORY

BLOOD FOR GENETIC TESTING AT THE NIDDK BIOREPOSITORY SHOULD BE SHIPPED ONLY IF THE SAMPLE <u>WAS NOT</u> COLLECTED AT V1B OR IF THE SAMPLE OBTAINED AT V1B WAS INADEQUATE (i.e, cell lines were not immortalized).

If participant has consented to have whole blood stored at NIDDK Biorepository but it is not necessary to collect the whole blood, Code question E2b as "01."

2 = Difficult Blood Draw 4 = Red Blood Cell Contamination

E1.	Did the participant	consent to ha	ve whole blood stored	at NIDDK Biorepository?		
	Yes		1			
	No		2 (END FORM)			
	Reasor	ns Code List*:	1= Not required	3 = Participant Refused	5 = Inadvertently Destroye	ed
			·	•		

Sample Type (Required Volume in Top Color Tube Type):	(a) Sample Ob <u>Yes</u>	tained:	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
2. Whole Blood for NIDDK Biorepository	1	2		i. Date of Blood Draw:
(6 mL of blood in 1 (6 mL) ACD tube)	(skip to c→)			
			(END FORM)	/
				MMDDYYYY
				ii. Blood Drawn By : (initials)
				, , ,
				iii. Gender of participant :
				Male1
				Female2

6 = Oversight

iv. Age of participant : \_\_\_\_ years