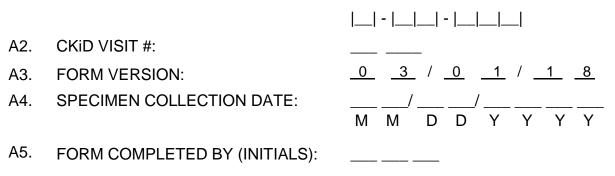
### SPECIMEN COLLECTION FORM for ODD Follow-up Visits (3, 5, 7...) (L31)

### 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



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)
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:

Samples:	Shipped to:	<u>Shipped:</u>
Serum (Biological)	NIDDK Biorepository	BATCHED (Ship in Jan, Apr, Jul or Oct)
Plasma (Biological)	NIDDK Biorepository	BATCHED (Ship in Jan, Apr, Jul or Oct)
Urine (Biological)	NIDDK Biorepository	BATCHED (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 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.

- B2. a. Urine pregnancy test date:

### 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 sample during CKiD visit.

Check that all information is correct on the urine collection tube and follow packaging instructions and ship to CBL.

Reasons Code List <sup>*</sup> :	1= Not required	4 = Collection Contamination	7 = Insufficient Volume
	2 = Difficult Urine Collection	5 = Inadvertently Destroyed	
	3 = Participant Refused	6 = Oversight	

Sample Type (Required Volume):	(a) Sample Obtained:		(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
	Yes	<u>No</u>	SEE CODE LIST ABOVE	
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?    Yes1    No2    ii. Time of Collection:   : 1 = am, 2 = pm

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

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

- 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)

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

#### 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

2

- 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)

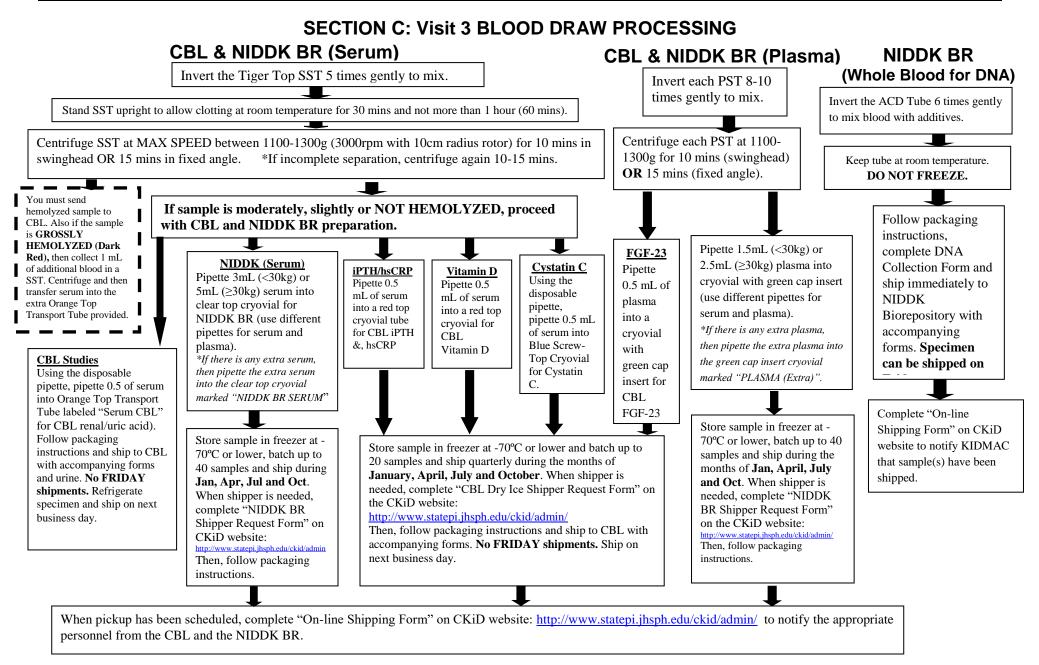
## **4** If participant did NOT consent to BIOLOGICAL samples and Genetic samples:

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)

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



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

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

Reasons Code List <sup>*</sup> :	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	(c) Additional Requirements:	
C2a.	Renal/Uric Acid Chemistries (1.0 mL in Tiger Top SST)	<u>Yes</u> 1 (skip to c→)	<u>No</u> 2	*SEE CODE LIST ABOVE	Indicate the appearance of the serum after centrifuging. 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 (skip to c→)	2	 (skip to C3)	Date Frozen:     /	
C3a.	Serum for iPTH, hsCRP & Vitamin D (2.0 mL of blood in Tiger Top SST)	1 (skip to c→)	2	(skip to C3b)	Date Frozen:      /	
C3b.	Plasma for FGF-23 (1.0 mL of blood in PST)	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	

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

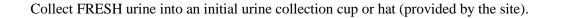
Reasons Code List <sup>*</sup> :	1= Not required	4 = Red Blood Cell Contamination	7 = Exceed maximum allowable volume
	2 = Difficult Blood Draw	5 = Inadvertently Destroyed	
	3 = Participant Refused	6 = Oversight	

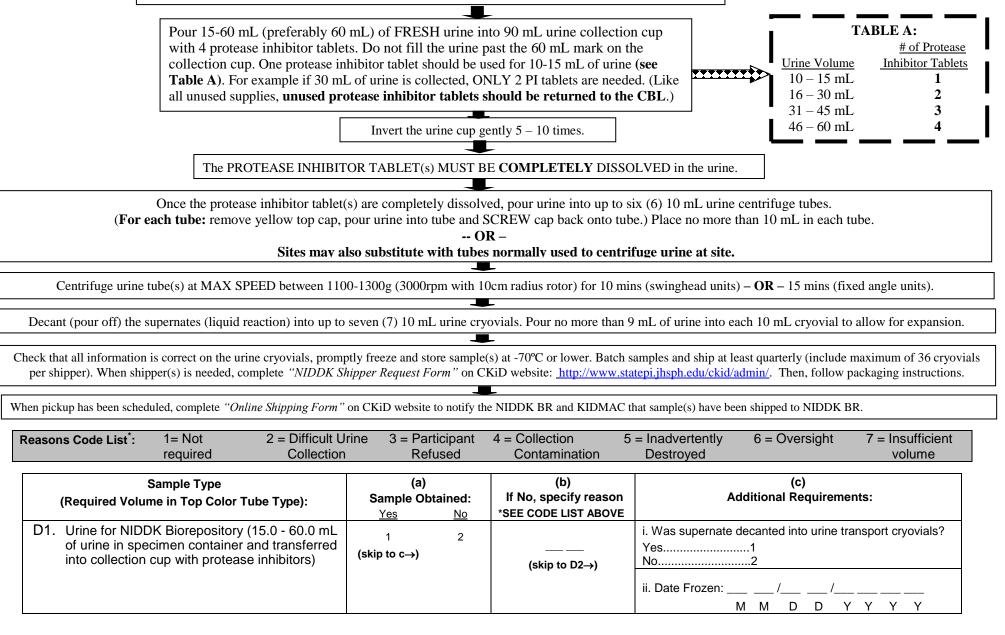
Sample Type (Required Volume in Top Color Tube Type):		(a) Sample Obtained:		(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:	
		Yes	No	SEE CODE LIST ABOVE		
C6.	Serum for NIDDK Biorepository (**6.0 mL or **10.0 mL of blood in Tiger Top SST)	1 (skip to c→)	2	(skip to C7)	Date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

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

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

## SECTION D: Visit 3 URINE COLLECTION AND PROCESSING FOR REPOSITORY





### **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).

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

Yes	1
No	2

→ Complete Local Urine Assay Results Form L06, ONLY if local labs are CLINICALLY INDICATED

### 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."

E1. Did the participant consent to have whole blood stored at NIDDK Biorepository?

Yes..... 1

No..... 2 (END FORM)

Reasons Code List <sup>*</sup> :	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 Ob <u>Yes</u>	tained: <u>No</u>	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:
E2. Whole Blood for NIDDK Biorepository (6 mL of blood in 1 (6 mL) ACD tube)	1 (skip to c→)	2	(END FORM)	i. Date of Blood Draw:   //